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The use of sonidegib in the treatment of patients with locally advanced basal cell carcinoma of the skin: an analysis of the impact on the Russian healthcare budget

M.Yu. Frolov[1], V.A. Rogov[1], O.I. Ivakhnenko[1], V.V. Ryazhenov[2]

[1] Volgograd State Medical University,
1 Pavshikh Bortsov Sq., Volgograd, Russia, 400066
[2] Sechenov First Moscow State Medical University (Sechenov University),
2 Trubetskaya Str., Bldg 8, Moscow, Russia, 119991

E-mail: clinpharmrussia@yandex.ru

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Budget Impact Analysis (BIA) is a key step in justifying the inclusion of new medicines in the list of vital and essential medicines (VED). It allows you to predict the financial consequences of the introduction of therapy and evaluate the effectiveness of resource allocation, which is of particular importance when using innovative antitumor drugs.

The aim. Implementation of the BIA of Healthcare of the Russian Federation of the use of sonidegib to assess the feasibility of inclusion in the list of VEDs for the treatment of patients with locally advanced basal cell carcinoma (laBCCs).

Materials and methods. In the pharmacoeconomic model developed for use in the Russian Federation, the BIA was conducted for healthcare in the Russian Federation based on comparative modeling of two scenarios: basic (all patients receive vismodegib) and alternative (phased introduction of sonidegib with an increase in the share to 50% by the third year). The time horizon is 3 years. Direct medical costs, price data from VED registers, government procurement, regulatory allowances, demographic and epidemiological parameters are taken into account. Additionally, a one-way sensitivity analysis was performed in the range of ±10% of key variables

Results. An analysis of the impact on the healthcare budget of the Russian Federation showed that the inclusion of sonidegib in the list of VED will lead to a 3.15% reduction in budget costs for the treatment of patients with laBCCs (-37,270,334 rubles or -387,440.81 USD) within the modeled patient population. The presented BIA results remain stable with changes in the price of comparison drugs, the total population size and the distribution of patient flow over the years, with a deviation from the baseline value of ±10%.

Conclusion. Modeling shows that the inclusion of the drug sonidegib in the list of VED leads to a reduction in the costs of the healthcare system with a possible increase in the tolerability of therapy and an expansion of the therapeutic arsenal for the treatment of laBCCs, i.e. it is justified from the point of view of clinical and economic consequences. The results obtained confirm its pharmacoeconomic validity as an alternative to vismodegib in the treatment of laBCCs.

Keywords: basal cell carcinoma of the skin; sonidegib; budget impact analysis; vital and essential medicines; targeted

Abbreviations: BCC — basal cell carcinoma; MNs — malignant neoplasms; BIA — budget impact analysis; VED — vital and essential medicines; laBCCs — locally advanced basal cell carcinoma; SmPC — summary of product characteristics; VEN List — List of Vital and Essential Medicines; MSP — manufacturer's selling price.

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Применение препарата сонидегиб при лечении пациентов с местно распространённым базальноклеточным раком кожи: анализ влияния на бюджет здравоохранения России

М.Ю. Фролов[1], В.А. Рогов[1], О.И. Ивахненко[2], В.В. Ряженов[2]

[1] Федеральное государственное бюджетное образовательное учреждение высшего образования «Волгоградский государственный медицинский университет» Министерства здравоохранения Российской Федерации, Россия, Россия, 400066, г. Волгоград, пл. Павших Борцов, д. 1

[2] Федеральное государственное автономное образовательное учреждение высшего образования «Первый Московский государственный медицинский университет имени И.М. Сеченова» Министерства здравоохранения Российской Федерации (Сеченовский университет), Россия, 119048, г. Москва, ул. Трубецкая, д. 8, стр. 2

E-mail: clinpharmrussia@yandex.ru

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Анализ влияния на бюджет (АВБ) является ключевым этапом обоснования включения новых лекарственных препаратов в перечень жизненно необходимых и важнейших лекарственных препаратов (ЖНВЛП). Он позволяет прогнозировать финансовые последствия внедрения терапии и оценивать эффективность распределения ресурсов, что имеет особое значение при применении инновационных противоопухолевых средств.

Цель. Проведение АВБ здравоохранения РФ применения сонидегиба для оценки целесообразности включения в перечень ЖНВЛП для терапии пациентов с местно распространённым базальноклеточным раком кожи (мрБКРК).

Материалы и методы. В разработанной для применения в условиях РФ фармакоэкономической модели проведён АВБ для здравоохранения РФ на основе сравнительного моделирования двух сценариев: базового (все пациенты получают висмодегиб) и альтернативного (поэтапное внедрение сонидегиба с ростом доли до 50% к третьему году). Временной горизонт — 3 года. Учтены прямые медицинские затраты, данные о ценах из реестров ЖНВЛП, государственные закупки, нормативные надбавки, демографические и эпидемиологические параметры. Дополнительно выполнен односторонний анализ чувствительности в диапазоне ±10% ключевых переменных

Результаты. АВБ здравоохранения РФ показал, что включение сонидегиба в перечень ЖНВЛП приведёт к снижению бюджетных затрат на лечение пациентов с мрБКРК на 3,15% (-37 270 334 руб. или -387 440,81 USD) в рамках моделируемой совокупности пациентов. Представленные результаты АВБ сохраняют устойчивость при изменении цены препаратов сравнения, размеров популяции в сумме и распределения пациентопотока по годам, при отклонении от базового значения ±10%.

Заключение. Моделирование показывает, что включение лекарственного препарата сонидегиб в перечень ЖНВЛП приводит к снижению затрат системы здравоохранения при возможном повышении переносимости терапии и расширении терапевтического арсенала для лечения мрБКРК, т.е. является обоснованным с точки зрения клинико-экономических последствий. Полученные результаты подтверждают его фармакоэкономическую обоснованность в качестве альтернативы висмодегибу в терапии мрБКРК.

Ключевые слова: базальноклеточный рак кожи; сонидегиб; анализ влияния на бюджет; ЖНВЛП; таргетная терапия

Список сокращений: БКРК — базальноклеточный рак кожи; ЗНО — злокачественные новообразования; ЛП — лекарственный препарат; АВБ — анализ влияния на бюджет; ЖНВЛП — жизненно необходимые и важнейшие лекарственные препараты; мрБКРК — местно распространенный базальноклеточный рак кожи; ОХЛП — общая характеристика лекарственного препарата; ГР ЖНВЛП — Государственный реестр жизненно необходимых и важнейших лекарственных препаратов; ОЦП — отпускная цена производителя.

INTRODUCTION

Basal cell carcinoma (BCC) is the most common type of skin cancer. According to expert estimates, it accounts for up to 80% of all non-melanoma malignant neoplasms (MNs) of the skin [1–4]. In the Russian Federation, BCC also has a leading position among skin MNs[1] [4], considering it as part of non-melanoma skin tumors. According to the National Cancer Registry, the incidence of BCC in the country has been steadily increasing over the past decades, which is associated

[1] Clinical Guidelines Basal cell carcinoma of the skin. Available from: https://cr.minzdrav.gov.ru/view-cr/467_3. (accessed July 20, 2025). Russian

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with both improved diagnostics and an increase in life expectancy: the total incidence of skin cancer in the Russian Federation is more than 50 cases per 100 thousand population, with BCC accounting for up to 70–80% of them[2]. According to 2022 data, the total number of new cases of non-melanoma skin cancer in Russia amounted to 79,399, while the standardized incidence rate was 26.49 per 100,000 population[3]. In the vast majority of patients, the disease is diagnosed at localized stages, when radical treatment is effective. However, a certain proportion of patients develop a locally advanced process that is not amenable to surgical or radiation treatment, which necessitates the use of systemic therapy [2, 4]. The proportion of patients with unresectable and recurrent forms of BCC, potential candidates for systemic therapy, is estimated by experts to reach 1–2% of the total population of patients [5].

Despite the relatively low potential of BCC for metastasis, some patients develop a locally advanced, recurrent, or unresectable course of the disease, which requires systemic targeted therapy [2]. Modern treatment strategies for advanced forms of BCC include the use of targeted therapy, which today represents a breakthrough in the treatment of metastatic, locally advanced, and unresectable forms of BCC [6, 8, 9]. Its mechanism is based on targeted effects on key molecular pathways involved in the development of the tumor, which makes the therapy highly effective and relatively safe. The main focus is on inhibiting the Hedgehog signaling pathway, which plays a key role in the pathogenesis of BCC. Thus, the use of medicines vismodegib and sonidegib provides an objective tumor response and control over its growth in cases where surgical or radiation treatment is impossible [6, 8, 10]. In particular, the BOLT study demonstrated the high efficacy of sonidegib in patients with unresectable disease [9], and the STEVIE study confirmed the stability of the effect of vismodegib with long-term therapy [11].

A comparative analysis of the pharmacokinetic and clinical properties of medicines indicates a number of differences that are potentially important for the healthcare system. Sonidegib has a longer half-life, which helps to reduce the frequency of visits to the doctor and potentially reduces the costs associated with monitoring treatment [9, 12]. In addition, the safety profile of sonidegib, according to the BOLT study, is characterized by a lower frequency of certain adverse events, such as alopecia and muscle cramps [13], which is also confirmed by real-world clinical practice studies in different countries [14].

Available pharmacoepidemiological data currently allow us to estimate the potential size of the target population for these medicines and to conduct economic assessments of their use. In 2025, an important publication by Orlova et al. was published, dedicated to the use of sonidegib in patients with locally advanced basal cell carcinoma (laBCC) in real clinical practice in the Russian Federation [15]. This multicenter prospective observational study makes it possible to adjust key parameters for budget impact analysis using local data reflecting current medical practice.

To assess the financial consequences of introducing sonidegib into the treatment of laBCC and the impact on the healthcare budget, a budget impact analysis (BIA) is required. This type of analysis complements the cost-effectiveness assessment and is of practical importance for healthcare authorities involved in the formation of the list of vital and essential drugs (VED) and in making decisions on financing new drugs[4, 5]. In this logic, our joint team of researchers in 2025 has already completed a study to assess the clinical and economic feasibility of using sonidegib in widespread clinical practice, which showed the clinical and economic advantages of its use in the 1-line therapy of patients with laBCC [17].

In the context of limited healthcare resources, the assessment of the budgetary consequences of introducing sonidegib into the system of preferential drug provision in the Russian Federation is of particular importance. Such an analysis allows not only to justify the medical feasibility of expanding the therapeutic arsenal for the treatment of laBCC, but also to demonstrate the economic sustainability of the solution, which is critical for its practical implementation[6].

Currently, there are no published data on the analysis of the impact on the budget of the Russian Federation of the use of sonidegib in the treatment of patients with locally advanced basal cell carcinoma of the skin, which determines the novelty of this study.

[2] Malignant neoplasms in Russia in 2023 (morbidity and mortality); Kaprin AD, Starinsky VV, Shakhzadova AO, editors. Moscow: Herzen Moscow Medical Research Institute − branch of the NMITS of Radiology; 2024. 276 p. Available from: https://oncology-association.ru/wp-content/uploads/2024/08/zis-2023-elektronnaya-versiya.pdf. Russian

[3] Ibid.

[4] Decree of the Government of the Russian Federation dated Aug 28, 2014 No. 871 (amended at July 25, 2024) “On Approval of the Rules for the Formation of Lists of medicines for medical use and the minimum range of medicines required for medical care”. Russian

[5] Guidelines for assessing the impact on the budget within the framework of the implementation of the program of state guarantees of free medical care to citizens, approved by Order No. 242-od of the Russian Ministry of Health dated December 29, 2018. Russian

[6] Ibid.

The present study is based on the hypothesis that the inclusion of sonidegib in the list of VED and its use within the state healthcare system of the Russian Federation for the treatment of patients with laBCC will expand therapeutic options in the 1-line of systemic treatment due to a clinically comparable, and in some parameters more preferable in terms of tolerability profile, targeted medicines; reduce the total direct medical costs of medicine therapy for this category of patients in a limited budget, and also support the implementation of the principles of personalized medicine by choosing the most suitable drugs, taking into account the individual characteristics of the patient, the profile of adverse events, and the treatment regimen. It is assumed that the partial replacement of vismodegib with sonidegib in the treatment of laBCC, subject to regulatory pricing conditions and procurement volumes, will not have a negative impact on the healthcare budget and will increase the clinical and economic efficiency of treatment.

THE AIM. To conduct an analysis of the impact on the healthcare budget of the Russian Federation of the use of sonidegib to assess the feasibility of inclusion in the list of VED for the treatment of patients with laBCC in the Russian Federation.

MATERIALS AND METHODS

Methodology

To achieve the objectives of the study, the following tasks were set:

1. To form basic and modeled scenarios for the use of drug therapy in patients with laBCC;
2. To determine the number of the target population of patients with laBCC potentially in need of therapy with drugs inhibiting the HH pathway;
3. To estimate the direct medical costs of drug treatment of patients in each of the scenarios;
4. To conduct a sensitivity analysis to assess the stability of the results while varying the key parameters of the model.

The BIA was performed taking into account the provisions of current regulatory documents and recommendations[7, 8].

The BIA was carried out using domestic data on morbidity, the cost of drug therapy and medical services, as well as the projected volume of medicine consumption. A feature of the BIA in the Russian Federation is the mandatory reliance on official sources (State Price Registers, Statistics from the Ministry of Health and RosStat) and the analysis of budgetary consequences in the context of approved standards of drug provision, which ensures the comparability of calculations and allows them to be integrated into the process of state pricing and procurement planning[9].

Uncertainty of input parameters was taken into account by performing a one-way scenario sensitivity analysis in the range of ± 10% of key variables. The format of presentation of results (absolute amounts and relative changes, year-by-year breakdown and difference by cost items) corresponds to the current Russian methodological requirements for BIA[10] and international practice (ISPOR [18], EUnetHTA[11]).

The model was developed in Microsoft Excel 2019 pro. It simulates the costs of the healthcare system of the Russian Federation in the treatment of patients with laBCC using vismodegib (basic scenario) and sonidegib (modeled scenario with phased implementation).

The analysis period is 3 calendar years (2026–2028). The scenarios were compared from the position of the state budget, including only direct medical costs for drug treatment of patients in the 1-line of therapy.

Description of the general structure and input parameters of the model

The model includes two scenarios:

1. Basic scenario: all patients receive vismodegib;
2. Modeled scenario: sonidegib is gradually introduced into therapeutic practice, starting from 10% in 2026 and up to 50% in 2028.

The input parameters of the pharmacoeconomic model are shown in Table 1. All data are normalized per one year of therapy per patient. A cohort approach is used without differentiation by outcomes, since the compared medicines belong to the same class and are comparable in clinical efficacy.

Cost estimation

The assessment of the impact on the healthcare budget of the Russian Federation of the use of sonidegib in widespread clinical practice in the event of the inclusion of the medicine in the list of VED was carried out taking into account only direct medical

[7] Requirements for the methodological quality of clinical and economic research of a medicines and research using the analysis of the impact on budgets of the budgetary system of the Russian Federation. Appendix No. 5.1 to the Rules for the Formation of Lists of medicines for medical use and the Minimum range of medicines required for Medical Care, approved by Decree of the Government of the Russian Federation dated August 28, 2014 No. 871. Russian

[8] Guidelines for assessing the impact on the budget within the framework of the implementation of the program of state guarantees of free medical care to citizens, approved by Order No. 242-od of the Russian Ministry of Health dated December 29, 2018. Russian

[9] Ibid.

[10] Ibid.

[11] EUnetHTA. Guidelines for Budget Impact Analysis of Health Technologies in the European Union. 2015. Available from: https://health.ec.europa.eu/health-technology-assessment/behind-hta-regulation_en

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costs for drug treatment in patients in the target population. It should be noted that the experience of researchers shows that additional costs incurred by the healthcare system are associated with the introduction of medicine, monitoring the patient, correcting side effects, etc. in drug of this pharmacotherapeutic group are not only practically identical, but also extremely low in the healthcare system of the Russian Federation. The above facts determine the choice of this approach to the selection of cost categories for BIA.

The calculation of the costs of therapy with vismodegib for the interventions under consideration was carried out on the basis of information on the methods of use and dosage regimens indicated in the SmPC[12] and clinical guidelines[13, 14]. As a source of information on the volume of purchases of the comparator vismodegib, data from IQVIA on monitoring public procurement for state and municipal needs for the period 2021–2025, provided by the company free of charge, were used.

As a source of information on prices for vismodegib, information on the current maximum selling price of the manufacturer (MSP) posted in the State Register of Registered Prices (as of March 13, 2025)[15] was used. Data on the MSP of sonidegib, planned for registration for the proposed medicine for inclusion, were provided by the manufacturing company, information on the methods of use and dosage regimens corresponds to the package leaflet — information for the patient[16] on the State Register of Medicines of the Russian Federation website[17]. The duration of 1 month was taken as 30.44 days. The calculations took into account the allowances established by the legislation of the Russian Federation (VAT 10%). Thus, the main parameters for calculating the costs of conducting 1 line of therapy for laBCC in the Russian Federation are shown in Table 2.

Number of patients

Data on the number of patients in the study group were obtained by calculation. For this purpose, an analysis of IQVIA data on purchases of vismodegib for the period from 2021 to 2025 was carried out. These data are presented in Table 3.

Table 2 shows that 1 369 packages of vismodegib were sold in 2021, 1 388 packages in 2022, 1 452 packages in 2023, 1 605 packages in 2024, and 2 023 packages in 2025.

Thus, it was found out the total number of courses of vismodegib purchased for the treatment of the study group of patients. Next, the number of patients that can be treated with this amount of medicine each year was calculated. We proceeded from the fact that the drug package contains 28 capsules, and the patient needs 365 capsules per year. The calculation results are also presented in Table 2. Based on the data obtained, a trend equation was calculated (using MS Excel 2019 pro).

The graph describing the trend and the trend equation is shown in Figure 1. Based on the trend equation, the forecast values of the total sales volume of vismodegib for the forecast period were calculated. The forecast data are presented in Table 2.

Thus, from the data in Figure 1 and Table 2, it can be seen that the forecast values of the number of patients, based on the expected purchase volume for the next 3 years, are 155, 167 and 179 patients, respectively.

It should be noted that the indicated number of patients includes patients with metastatic and unresectable BCC. At the same time, during the literature search, the most convincing data on the ratio of the number of patients with locally advanced and metastatic forms are presented in the work of Orlova et al., according to the Blokhin National Medical Research Center of Oncology [15]. This medical institution is one of the largest in the Russian Federation in the field of providing oncological care, respectively, we consider it possible to transfer their data to the general population of patients. The work notes that among all cases of BCC, 94 (3.4%) cases of the forms of the disease under consideration were registered: with a locally advanced form of BCC — 78 (2.8%) patients and a metastatic form — 16 (0.6%) patients. Thus, the proportion of patients with a locally advanced form is — 82.98% (78 out of 94 patients). Based on this, the number of patients in the model in the forecast period will be:

1. In 2025 / 26, 82.98% of 155 patients will be 129 patients
2. In 2026 / 27, 82.98% of 167 patients will be 139 patients
3. In 2027 / 28, 82.98% of 155 patients will be 149 patients.

[12] General characteristics of the Erivage, 150 mg, capsules. Corresponds to the expert report dated October 19, 2022 No. 24523 (sequence 0007). Available from: https://lk.regmed.ru/Register/EAEU_SmPC. Russian

[13] Clinical Guidelines Basal cell carcinoma of the skin.

[14] General characteristics of the Erivage, 150 mg, capsules. Corresponds to the expert report dated October 19, 2022 No. 24523 (sequence 0007).

[15] Vismodegib. State Register of Registered Prices. Available from: https://grls.minzdrav.gov.ru/PriceLims.aspx

[16] Leaflet; information for the patient Odomzo, 200 mg, capsules. Corresponds to the expert report dated July 02, 2025 No. 16397 (sequence 0005). Available from: https://lk.regmed.ru/Register/EAEU_SmPC

[17] Sonidegib. State Register of Medicines of the Russian Federation. Available from: https://grls.rosminzdrav. ru/Grls_View_v2.aspx?routingGuid=e000a8be-5db8-41a8-8c06- 0c06d4f83b05

Table 1 — Input parameters of the pharmacoeconomic model

Parameter	Value	Source
Period of time	3 years (2026–2028)	Own calculations
Population	Patients with laBCC suitable for systemic therapy	Section 5
Object of analysis	Costs of targeted therapy (vismodegib, sonidegib)	SmPC, VED List dated July 29, 2025
Price sources	VED List (vismodegib), manufacturer data (sonidegib)	[16], manufacturer
Model type	Deterministic cohort Excel model	Own development

Note: SmPC — summary of product characteristics; VED — List of Vital and Essential Drugs; laBCC — locally advanced basal cell carcinoma.

Table 2 — The cost of drugs used in accounting for the costs of drug therapy of 1-line of locally advanced basal cell carcinoma of the skin in the Russian Federation

INN	form, dosage	VEN List price without VAT, rubles (USD)	Price per capsule without / with VAT, rubles (USD)	Costs per 1 month of therapy, rubles with VAT (USD)	Costs per 1 year of therapy, rubles (USD)	Difference Δ
Vismodegib	Capsules 150 mg, No. 28	198,051.61 (2058.83)*	7 073.27 / 7780.60 (73.53 / 80.88)*	236,817.11 (2461.81)*	2 841,804.88 (29 541.76)*	–
Sonidegib	Capsules 200 mg, No. 30	189,158.00 (1966.38)*	6 305.28 / 6935.80 (65.55 / 72.10)*	211,104.20 (2194.52)*	2 533,249.96 (26 334.20)*	-10.86%

Note: * — the average exchange rate of the dollar against the ruble was used in the calculations: 96.1962 rubles per 1 USD for October 2024; ** — costs per 1 administration, rubles *** — in the calculations, the duration of 1 month was taken as 30.44 days in accordance with Federal Law No. 107-FZ of 06/03/2011 "On Calculating Time". INN — international nonproprietary name; VED List — List of Vital and Essential Drugs.

Table 3 — The volume of purchases of the vismodegib according to IQVIA for the period 2021–2025

Indicator	05.20–05.21	05.21–05.22	05.22–05.23	05.23–05.24	05.24–05.25	1 forecast year (2025 / 26)	2 forecast year (2026 / 27)	3 forecast year (2027 / 28)
Number of vismodegib packages purchased during the period	1 369	1 388	1 452	1 605	2 023	2025	2177	2330
Number of annual courses	105	106	111	123	155	155	167	179

Table 4 — Structure of the flow of patients receiving 1-line therapy for locally advanced basal cell carcinoma of the skin in the Russian Federation, used in the BIA model, *n* (%)

Medicine	Basic scenario		
	1 year	2 year	3 year
Sonidegib	0 (0%)	0 (0%)	0 (0%)
Vismodegib	129 (100%)	139 (100%)	149 (100%)
	Modeled scenario		
	1 year	2 year	3 year
Sonidegib	13 (10%)	42 (30%)	75 (50%)
Vismodegib	116 (90%)	97 (70%)	75 (50%)
Total	129 (100%)	139 (100%)	150 (100%)

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Table 5 – Results of the BIA of patients receiving 1-line therapy for locally advanced basal cell carcinoma of the skin in the Russian Federation, taking into account the full cost of therapy per year, rubles (USD)

Basic scenario				
Medicine	1 year	2 year	3 year	Total
Sonidegib	0.00	0.00	0.00	0.00
Vismodegib	366 592,829.34 (3 810 886.81)*	395 010,878.13 (4 106,304.39)*	423 428,926.92 (4 401,721.969)*	1 185 032,634.39 (12 318,913.16)*
Total	366 592,829.34 (3 810,886.81)*	395 010,878.13 (4 106,304.39)*	423 428,926.92 (4 401,721.969)*	1 185 032,634.39 (12 318,913.16)*
Modeled scenario				
	1 year	2 year	3 year	Total
Sonidegib	32 932,250 (342,344.60)*	106 396,498 (1 106,036.40)*	189,993 747 (1 975,064.96)*	329 322,495 (3 423,445.99)*
Vismodegib	329 649,366 (3 426,843.95)	275 655,073 (2 865,550.54)*	213 135,366 (2 215,631.86)*	818 439,805 (8 508,026.36)*
Total	362 581,615 (3 769,188.55)	382 051,572 (3 971,586.94)*	403 129,113 (4 190,696.86)*	1 147 762,300 (11 931,472.35)*
Difference Δ	-4 011,214 (-41,698.26)*	-12 959,306 (-134,717.4463)*	-20 299,814 (-211,025.11)*	-37 270,334 (-387,440.81)*
Difference Δ,%	-1.09%	-3.28%	-4.79%	-3.15%

Note: * — the average exchange rate of the dollar against the ruble was used in the calculations: 96.1962 rubles per 1 USD for October 2024.

Table 6 – Results of the sensitivity analysis of the results of the BIA of the healthcare system of the Russian Federation of the use of the sonidegib in the treatment of patients with locally advanced basal cell carcinoma of the skin

Dynamic parameter	Value of the changed parameter,%			BIA result (savings over 3 years, rubles)	
	Baseline	-10%	10%	-10%	10%
Price of sonidegib	189.158.00 (1 966.38)*	170.242.46 (1 769.74)*	208,074.12 (2 163.02)*	-70 202,584 (-729,785.41)*	-4 338,084 (-45,096.21)*
Price of vismodegib	198 051.61 (2 058.83)*	178246.44 (1 852.95)*	217,856.77 (2 264.71)*	-611,217 (-6 353.86)*	-73 889,145 (-768,108.77)*
Number of the target population for 3 years, people.	417	375	459	-34 093,209 (-354413.26)*	-42 938,995 (-446,368.93)*
Proportion of patients switched to sonidegib in year 1,%	10.0%	9.0%	11.0%	-36 941,793 (-384,025.49)*	-37 558,569 (-390,437.14)*
Proportion of patients switched to sonidegib in year 2,%	30.0%	27.0%	33.0%	-32 007,589 (-332,732.36)*	-33 857,916 (-351,967.29)*
Proportion of patients switched to sonidegib in year 3,%	50.00%	45.0%	55.0%	-37 623,309 (-391,110.13)*	-42 249,125 (-439,197.45)*

Note: * — the average exchange rate of the dollar against the ruble was used in the calculations: 96.1962 rubles per 1 USD for October 2024.

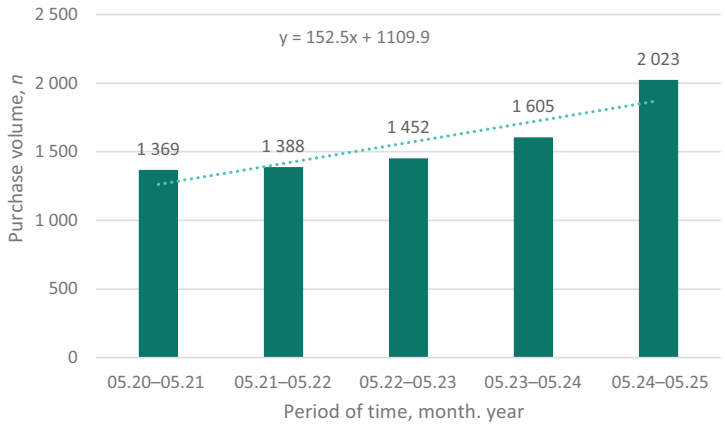

Figure 1 – Dynamics of the purchase volume of the vismodegib (150 mg No. 28) according to IQVIA for the period from 2021 to 2025 with a trend equation.

RESULTS

As part of the BIA model prepared by us, the calculation of expenses for the basic scenario, which includes vismodegib capsules 150 mg, 1 capsule 1 per day for the entire period under consideration, as part of the 1-line of therapy for laBCC, was performed.

At the same time, the modeled scenario includes the use of sonidegib in the 1-line of therapy in the mode of capsules 200 mg, 1 capsule 1 per day for the entire period under consideration.

The calculation of the costs of drug therapy with vismodegib for the interventions under consideration was carried out on the basis of information on the methods of use and dosage regimens indicated in the SmPC[18] and clinical guidelines "Basal cell carcinoma of the skin"[19].

The number and mechanism of calculation of the studied population of patients are described in the previous section "Number of patients".

Analysis of the literature data showed that the new medicine has high efficacy [6, 7] against the background of a significantly lower price per similar course of therapy compared to the competitor, which creates market prerequisites for a rapid replacement of vismodegib with sonidegib. Based on this, in Table 4 we see that in the basic scenario, all patients are on vismodegib therapy throughout the entire study period, while in the modeled scenario, starting from year 1, the proportion of sonidegib is rapidly increasing, reaching 50% by year 3, i.e. replaces half of the share of compared medicines. This distribution is an empirical assumption of the research team and is an assumption of the study.

Based on the forecast number of patients presented above in the "Number of patients" section, as well as the basic and modeled scenarios of their distribution presented in Table 4, we have the following structure of the patient flow, presented in Table 4.

Based on the available data on the structure and number of patients (see Table 4), as well as the cost of annual courses of therapy with compared medicines (see Table 2), a calculation was made of the amount of budget expenditures required for the treatment of patients in the study group under the basic and modeled scenarios. The results are presented in Table 5.

From the data in Table 5, it can be seen that the use of sonidegib in the 1-line therapy of laBCC provides savings to the healthcare budget of 3.15% (-37 270,334 rubles or -387,440.81 USD)

[18] General characteristics of the Erivage, 150 mg, capsules. Corresponds to the expert report dated October 19, 2022 No. 24523 (sequence 0007).

[19] Clinical Guidelines Basal cell carcinoma of the skin.

Sensitivity analysis of the results obtained

The stability of the results obtained was confirmed by the method of one-way sensitivity analysis. The parameters that were changed during the analysis, as well as the degree of their change, are presented in Table 6.

Thus, the presented results of the BIA remain stable even with the changes of the price of compared medicines, the size of the population in total, and the distribution of patient flow by year, with a deviation from the base value of ± 10%.

DISCUSSION

The obtained results of the BIA of the healthcare system of the Russian Federation when using sonidegib in the treatment of laBCC confirm its pharmacoeconomic validity as an alternative to vismodegib. Especially, taking into account the reduction of total budget expenditures by 3.15%, the transfer of some patients to sonidegib therapy may be a rational step in the framework of expanding therapeutic options.

The key argument in favor of sonidegib is its clinical profile. The BOLT study demonstrated that sonidegib has high efficacy in patients with unresectable BCC, achieving an objective response in more than 56% of patients with a disease control duration of up to 22 months [9]. At the same time, the tolerability profile was recognized as acceptable, with a lower frequency of pronounced side effects, including muscle cramps and alopecia [6, 12]. It is important that, assessing this clinical study [9], the respondent doctors expressed their opinion that these data were extremely significant for choosing the treatment of patients with laBCC [19].

The pharmacokinetic features of sonidegib also deserve attention. The medicine is characterized by a longer half-life (approximately 28 days) [20], which may reduce the frequency of visits to the doctor and the need for dosage adjustment compared to vismodegib [2, 7]. This may have a positive impact on patient loyalty to therapy and reduce indirect costs. Regarding the assessment of the safety of the compared medicines, information continues to be accumulated, the different spectrum of toxicity is the subject of close study and serves as the basis for choosing between them with individual patients [4, 21].

Earlier studies of the efficacy and safety of vismodegib showed stable control over the disease with long-term use, but were accompanied by a significant frequency of adverse events [9, 10, 22]. In particular, in one of the studies [6], the frequency

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of objective response to vismodegib therapy was 47.6% (95% CI: 35.5–60.6), and when patients were transferred to sonidegib due to toxicity, clinical efficacy was maintained: the frequency of objective response reached 56%, disease control — 75%, with a more favorable tolerability profile. Data from a multicenter retrospective study in China [4] clarify that adverse events during sonidegib therapy occurred in 89% of patients, but were predominantly mild and moderate in severity, no serious complications were noted, and the median duration of treatment was 28 weeks. An additional comparative analysis of adverse event profiles based on the FAERS database [23] showed that muscle spasms and dysgeusia (taste distortion) were most often recorded for both Hedgehog inhibitors, but the differences between vismodegib and sonidegib concerned lesions of the nervous system, gastrointestinal tract, skin, and urinary system. These results confirm the clinical relevance of individual drug selection and indicate the potential advantages of sonidegib in case of vismodegib intolerance. Similar results were obtained as a result of the analysis of actual data from the French national register CARADERM[20] [24].

In addition, tumor resistance to Hedgehog inhibitor therapy may be associated with mutations in the *SMO* gene, which requires a strategy of changing the drug as part of an individualized treatment selection [1, 3, 25].

It is important to note that the inclusion of new medicines in the drug provision system should be accompanied by an analysis of real clinical efficacy and cost assessment. As real-world clinical practice data on the use of sonidegib in the Russian Federation accumulate, a more accurate assessment of its impact on the overall costs of the healthcare system, as well as on the survival and quality of life of patients, will become possible. At the same time, it is important to take into account that the clinical studies underlying the registration of the medicine were conducted on a selected population and under controlled protocols [5, 7, 23], which may differ somewhat from routine clinical practice. Such studies on the use of sonidegib are being conducted in different countries [23, 26, 27], supplementing information from randomized clinical trials.

Available sources note the potential of sonidegib as a 2nd line medicine in patients forced to discontinue vismodegib therapy due to intolerance. It was previously shown [9] that among patients who discontinued vismodegib treatment due to toxicity, switching to sonidegib was accompanied by the maintenance of clinical efficacy: the frequency of objective response reached 56%, and disease control was recorded in 75% of patients with a more favorable tolerability profile.

Thus, expanding access to sonidegib may be strategically justified, given the clinical and pharmacological advantages, possible reduction of side effects, improvement of patients' quality of life, and potential reduction of indirect costs associated with hospitalizations, treatment of complications, and palliative care [7, 9, 14].

Study limitations

Like any pharmacoeconomic modeling, the study has a number of limitations that must be taken into account when interpreting the results obtained. Some of the limitations are related to the availability and completeness of data. The number of the target population was calculated on the basis of available epidemiological data and mathematical modeling, since official statistics on the proportion of patients with locally advanced and unresectable BCC in the Russian Federation are not publicly available. The study is based on data from international clinical trials (BOLT [9], STEVIE [11], etc.), since there are no large post-registration studies in the Russian Federation reflecting the clinical efficacy and safety of the medicine in real clinical practice. In such cases, differences in the population characteristics of patients and adherence to treatment are always possible, which may affect the reproducibility of the results obtained. Direct medical costs were estimated on the basis of available prices in the VEN List and data provided by the manufacturer of sonidegib. Actual purchase prices in various subjects of the Russian Federation may differ depending on contractual terms, regional allowances, and the level of competition at auctions. The analysis did not include indirect costs (indirect expenses), such as productivity losses, care and rehabilitation costs. Only direct medical costs for drug therapy were taken into account, as is customary in the framework of the BIA, carried out in accordance with the provisions of the current version of the Decree of the Government of the Russian Federation No. 871[21] for the purposes of inclusion in the list of VED.

[20] CARADERM . Available from: https:// www.caraderm.org/

[21] Decree of the Government of the Russian Federation dated August 28, 2014 No. 871 (amended at July 25, 2024) "On Approval of the Rules for the Formation of Lists of medicines for medical use and the minimum range of medicines required for medical care". Russian

CONCLUSION

Modern methods of treatment of metastatic and BCC are focused on the use of targeted therapy aimed at inhibiting the Hedgehog signaling pathway. The main medicines are vismodegib and sonidegib, which have proven their efficacy in clinical studies, providing control over tumor growth and improving survival in patients for whom traditional methods of treatment, such as surgery and radiation therapy, are not available.

Sonidegib has a number of advantages over vismodegib. First of all, it has a longer half-life, which allows less frequent dosage adjustments and potentially reduces the frequency of visits to the doctor. This may reduce the overall medical expenses associated with monitoring therapy. In addition, clinical studies show that sonidegib may be better tolerated, characterized by a lower frequency and severity of some side effects, such as alopecia and muscle cramps, which contributes to a better quality of life for patients during long-term treatment.

An analysis of the impact on the healthcare budget showed that the inclusion of sonidegib in the list of VED will lead to a reduction in budget expenditures for the treatment of patients with laBCC by 3.15% (-37 270,334 rubles or -387,440.81 USD) within the framework of the modeled population of patients. Analysis of the literature data showed that expanding therapeutic options through the introduction of sonidegib can increase the effectiveness of treatment and improve the quality of life of patients, which will lead to a reduction in indirect costs associated with complications, hospitalizations, and palliative care. The results of the study can serve as a clinical and economic justification for the inclusion of sonidegib in the list of VED, which will expand the availability of targeted therapy and improve the quality of medical care for patients with locally advanced basal cell carcinoma of the skin.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHORS’ CONTRIBUTION

Maksim Yu. Frolov — design development, collection and critical analysis of literature and regulatory legal documents, data collection and analysis, modeling and interpretation of results, writing, draft editing, final approval of the article; Vladimir A. Rogov — critical analysis of literature, making comments of intellectual content, draft editing; Vasily V. Ryazhenov — critical analysis of literature, making comments of intellectual content, draft editing; Oksana I. Ivakhnenko — critical analysis of literature, making comments on intellectual content, draft editing. All authors confirm that their authorship meets the international ICMJE criteria (all authors made a significant contribution to the development of the concept, conduct of the study and preparation of the article, read and approved of the final version before the publication).

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AUTHORS

Maxim Yu. Frolov — Candidate of Sciences (Medicine), Assistant Professor of the Department of Clinical Pharmacology and Intensive Care of the Volgograd State Medical University. ORCID ID: 0000-0002-0389-560X. E-mail: clinpharmrussia@yandex.ru

Vladimir A. Rogov — Candidate of Sciences (Pharmacy), Assistant Professor of the Department of Pharmaceutical Business Organization, Pharmaceutical Technology and Biotechnology of the Volgograd State Medical University. ORCID ID: 0000-0002-2164-2323. E-mail: var85@ya.ru

Oksana I. Ivakhnenko – Assistant of the Department of Regulatory Relations in the field of circulation of medicines and medical devices of the Sechenov First Moscow State Medical University (Sechenov University); Master of Law. ORCID ID: 0000-0002-9483-3171. E-mail: oii@hta-expert.ru

Vasily V. Ryazhenov — Doctor of Sciences (Pharmacy), Head of the Department of Regulatory Relations in the Field of Circulation of Drug Products and Medical Devices of the Sechenov First Moscow State Medical University (Sechenov University). ORCID ID: 0000-0002-1278-5883. E-mail: 5052568@mail.ru