EXCERPT

Healthle — Japan Pharma Market Intelligence

Lurasidone Hydrochloride (Latuda Tablets): Generic Entry Landscape in Japan 2026

Lurasidone hydrochloride (Latuda tablets 20 mg, 40 mg, 60 mg and 80 mg; Sumitomo Pharma)

Report	HDB-R-0001 · 2nd edition (November 2026). Original language: Japanese
Data as of	November 2026 (market data: fiscal years to FY2024 and monthly data to June 2025; NHI prices to the April 2026 revision)
Full report	Main volume 103 pages · Data volume 295 pages · 97 figures and 274 tables · Excel workbook with 371 sheets
This excerpt	English translation of the parts we already publish on our website: executive summary, the full table of contents and the full list of figures and tables. The body chapters and the data volume are not included.

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About this excerpt

The report brings together, with sources, the public information used when considering generic entry. The main volume (103 pages) covers the re-examination period and patents, market size, NHI prices, competition, four precedent molecules, overseas developments, and API and formulation, with key points, figures and tables for each topic. The 2nd edition adds Chapter 10, a market and generic entry outlook (estimate, with the central value and the 10th–90th percentile range) built from the distribution of precedents. The data volume (295 pages) contains the full tables, the original texts of laws, notifications and patent publications, and the estimation methods and assumptions.

Written for planning, business development, regulatory affairs and intellectual property staff at generic manufacturers and API trading companies.

Part	Size
Main volume (executive summary, Chapters 1–11)	103 pages
Data volume (D0–D11, Appendices A–E)	295 pages
Figures and tables	97 figures, 274 tables (listed in full on pages that follow)
Excel workbook	371 sheets (the data behind each figure and table)

The original report is in Japanese. Page numbers in the table of contents refer to the Japanese original. This excerpt was translated by Healthle; dates, patent numbers and company names are as in the original, and amounts are converted from units of JPY 100 million (oku-yen) to JPY billion (for example, 118.2 oku-yen = JPY 11.82 billion).

What the full report covers

- **Exclusivity: re-examination period and patents (Chapter 3)** — Extension of the re-examination period, the eight patents with term extensions and their expiry dates, a timeline, the status of 130 third-party patent publications, and the results of searches for trials and litigation. The original texts of the claims and notifications are in the data volume.
- **Market size and trends (Chapter 2)** — Estimated sales value (NDB Open Data quantity × NHI price) by fiscal year, strength, care setting, sex and age group. Like-for-like growth, decomposition into volume and unit price, API-equivalent quantity, and comparison with company-disclosed revenue. Prescription volume for April–June 2025 from the monthly release (including publicly funded care).
- **NHI price (Chapter 4)** — Pricing at listing, price history and revision rates, key points of the pricing rules for generics, listing prices of the four precedent molecules, and values calculated by applying the rates in the pricing rules.
- **Competition (Chapter 5)** — Market size (estimated sales value) and trends by molecule for atypical antipsychotics, company shares, and the position of lurasidone among them.
- **Precedents of generic entry (Chapter 6)** — For the four precedent molecules: expiry dates of the re-examination period and patents, first generic NHI listing dates, number of products at listing, price ratio to the originator, subsequent prices, and volume and value shares.
- **Overseas developments (Chapter 7)** — US Orange Book patents and the date from which generics could be marketed, litigation and settlements, number of ANDA approvals, originator sales after generic entry, Europe and the UK.
- **API and formulation (Chapter 8)** — Registration status of Japanese MFs, US DMFs and European CEPs, formulation composition, dissolution and stability, food effect, and key points of the bioequivalence guideline.

- **Market and entry outlook (estimate) (Chapter 10 and data volume D10)** — Market size for FY2025–FY2036, scenarios for the timing of the first generic listing (S1–S4), distribution of the number of generic brand names, generic volume share, price ratio and value, volume and value per company by entry order, API-equivalent quantity, and an indicative timeline. All values are Healthle estimates, shown as a central value with a range (10th–90th percentile). The report does not name which companies will enter. Methods, assumptions, the distribution of precedents and the published data used for updates are in the data volume.
- **Points to check (Chapter 11, Appendices D and E)** — For each topic, the current status, related regulatory rules and unconfirmed items; items readers need to check themselves; 105 unconfirmed items with where to confirm them; and a list of sources.

Limits of the report (as stated in the original)

- The report does not judge whether or when to enter, whether a particular product falls within the scope of a patent, or what the NHI price will be. Regulatory rules are quoted from the original texts as general rules.
- Market values and quantities are Healthle estimates, calculated by multiplying NDB Open Data quantities by NHI prices. They are not company sales, shipments or wholesale results. Chapters 1–9 exclude care funded only by public expenditure; the outlook in Chapter 10 and the monthly quantities in section 2.11 of Chapter 2 include it.
- The outlook in Chapter 10 is a Healthle estimate built from the stated assumptions and the distribution of past precedents. It does not promise future market size, timing of entry or number of entrants, and it does not address whether any individual company will enter.
- Items that could not be confirmed are listed in Appendix D as 105 unconfirmed items (for example, the wording on acceptance of applications, the dissolution test conditions in the approved specifications, and the terms of the US settlement).
- The report has not been reviewed by a patent attorney or a chemistry specialist. Patent, regulatory and legal judgements require professional advice.

Commissioned reports

We prepare reports with the same structure for the molecule and questions you specify, in English. Contact us at www.healthle.jp/en or www.healthle.jp/market-research. The Japanese edition of this report is on sale at www.healthle.jp/drug-database/research/hdb-r-0001.

Executive summary

Translated from the nine-page executive summary of the original (pages 6–14). The Japanese pages are reproduced after this section.

S1 Re-examination period expires on 24 March 2030. FY2024 estimated sales value JPY 11.82 billion; no generics on the NHI price list

Issue	Current position (confirmed facts and estimates)	Relevant regulatory rules	Not confirmed
Exclusivity	The re-examination period runs until 2030-03-24. The 8 patents with a patent term extension (PTE) have expiry dates of 2028-08-20 to 2035-10-10 (4 before 2030-03-24, 4 after). No record of invalidation trials, patent oppositions or court judgments was found in J-PlatPat or the court case-law search.	The patents considered in approval review under the notification (2025-10-08) are "substance patents or use patents". "The existence of a patent is judged as of the scheduled approval date."	Approval of the pediatric dosage and administration (application filed 2026-03-30) and any re-examination period that follows. Pending cases. Other companies' patent publications that mention the term only in the full text (see S3).
Application and listing	The NHI price list (October 2026 edition) contains no generic of lurasidone hydrochloride. No announcement of a Japanese application or development was found.	Generic applications are accepted in two rounds a year. The standard administrative processing time for a new approval application is "one year". NHI listing is "standardly in June and December" (ibid.).	Whether any product is under application (not disclosed). Any official rule setting the date from which applications are accepted after expiry of the re-examination period.
Market size	FY2024 estimated sales value JPY 11.82 billion, 54.176 million tablets, API-equivalent quantity 1,554.9 kg (as hydrochloride). Like-for-like growth +22.9% and +12.5%.	—	Actual sales, the value of care funded only by public expenditure, breakdown by indication, fiscal-year values for FY2025 onward (monthly release covers April–June 2025 only).
NHI price	April 2026: 40mg JPY 288.1. For the four precedent molecules, the ratio of the NHI price at listing (generic ÷ originator, tablets) was 0.32–0.54.	The NHI price of a generic listed for the first time is 50/100 of the price calculated with the most similar comparator drug as the comparator (40/100 for oral drugs when the number of products exceeds 7).	The originator's NHI price and pricing basis at the time of listing. The number of products listed at the same time.
Precedents	For all four precedent molecules, generics were first listed after the later of expiry of the re-examination period for the first indication and expiry of a PTE patent (one patent extracted per molecule): 1.8–16.8 months after the later date, and 119–123 days after generic approval (calculated). FY2024 generic volume share was 70.8–92.6%. For blonanserin, there is a product ("DSPB") that the company's announcement describes as an AG.	— (records of the four molecules)	The circumstances that determined listing timing. Volume share for FY2021 and earlier (lower bound only). Company policy regarding lurasidone.
Overseas	The date from which generics could be marketed in the US was 2023-02-20. North American revenue fell from JPY 198.5 billion to JPY 6.7 billion.	— (a different system from Japan; Chapter 7)	Settlement terms; European launch dates.

API and formulation	There are 3 Japanese Master Files (MF holder: HETERO DRUGS LIMITED) and 36 US DMFs. Dosing is once daily after a meal; administration after a meal gave a 2.4-fold Cmax and a 1.7-fold AUC.	Japan's bioequivalence study guideline requires fasting in principle. Fed administration applies where, for example, "administration after meals is specified in the dosage and administration, and bioavailability is markedly lower under fasting administration".	Dissolution test conditions in the approved specifications (not found in public documents). The MF in-country caretaker and supply availability.

S2 Re-examination period runs until 24 March 2030. The 8 PTE patents expire between August 2028 and October 2035

The re-examination period and patents are separate systems, and their dates are set separately. We placed the dates from public records on a single timeline (Chapter 3: dates and the corresponding regulatory rules).

Key point. The re-examination period was 8 years at approval and was extended to 24 March 2030 by the notification of 18 June 2021 (Notification 薬生薬審発0618第5号). Of the 8 patents, 4 have expiry dates before 2030-03-24 and 4 after (date comparison). Substance patent 2800953 expired on 2011-06-27.

Regulatory rule. The notification of 8 October 2025 states that the patents considered in approval review are "substance patents or use patents" and that "the existence of a patent is judged as of the scheduled approval date". The body of the notification says nothing about process or formulation patents. Patent types in this report are classified by the wording of the claims.

Not confirmed. On 30 March 2026, a partial change application was filed to add a pediatric dosage and administration for schizophrenia. As of 11 November 2026, no record of approval was found. The only PTE applications on J-PlatPat are the 32 filed in 2020. The timing of approval and the re-examination period to be designated at approval are not confirmed.

S3 No record of invalidation trials or litigation for the 8 PTE patents. 130 other-company publications include "lurasidone" in the claims

We searched J-PlatPat and the court case-law search for the legal status and dispute records of Sumitomo Pharma's patents and for other companies' patents and applications (Chapter 3).

Key point (legal status). For all 8 PTE patents, the J-PlatPat registration information states "this right has not been extinguished", and the right holder is Sumitomo Pharma Co., Ltd. No record of an invalidation trial, PTE invalidation trial, correction trial, patent opposition or advisory opinion (hantei) was found for any of the 8 (the only trial record is one appeal against examiner's refusal for Patent 6470164, in which the applicant contested a refusal). No lurasidone patent case was found in the full-text search of trial decisions or in the court case-law search. File inspection requests are recorded 4 times for Patent 6470164 (2024–2026) and once for Patent 5855670 (requester not shown).

Key point (other companies' patents). We checked the publications and prosecution history of all 130 other-company documents with the term in the claims. Only 2 have lurasidone as their subject and are granted and in force: Patent 6594351 (process) and Patent 7918561 (orally disintegrating film). In the other 22 that are in force with the term in the claims of the granted patent, lurasidone appears in a list alongside other drugs or as one member of a group; claim 1 of Patent 7305560 is a two-component group of lurasidone and brexpiprazole, and in Patent 6416762, dependent claim 3 limits the drug to lurasidone.

Not confirmed. For Patent 4745661, the year(s) covered by, and the reason for, the 2022 procedural dismissal of a patent fee payment. The patent register, the requesters of file inspections, and cases not listed in the searches or still pending. About 800 publications that mention the term only in the full text, patents that describe the compound only by formula or another chemical name without the term, and unpublished applications (Appendix D).

S4 FY2024 estimated sales value JPY 11.82 billion. Like-for-like growth of +22.9% and +12.5%, driven by volume

Values are estimated sales value calculated as NDB Open Data volume × NHI price. All strengths and all care settings were published only for FY2024, so year-on-year comparisons use like-for-like values (common strength × care setting) (Chapter 2).

Estimate. FY2024 volume was 54.176 million tablets, and the API-equivalent quantity was 1,554.9 kg (as hydrochloride). Outpatient prescriptions dispensed outside the hospital account for 84.5% of estimated sales value.

Estimate. The +12.5% from FY2023 to FY2024 breaks down into a volume effect of +15.5% and a unit-price effect of −2.9%.

Key point. Company-disclosed domestic sales (ex-factory price basis) were JPY 13.2 billion in FY2024. Estimated sales value for FY2022–FY2024 was 85–90% of the company-disclosed domestic sales for each year (calculated).

S5 Lurasidone ranks 2nd by estimated sales value among 11 oral atypical antipsychotics. 5 molecules have no generics listed

We extracted drugs in the same therapeutic area as lurasidone by molecule and organized FY2024 estimated sales value by originator and generic (Chapter 5).

Estimate. FY2024 estimated sales value for the 11 oral molecules was JPY 73.14 billion. Lurasidone ranks 2nd at JPY 11.82 billion (16.2%); 1st is brexpiprazole (JPY 21.92 billion).

Key point. The 5 molecules with no generics listed are brexpiprazole, lurasidone, paliperidone, clozapine and asenapine, with combined estimated sales value of JPY 47.26 billion (64.6% of the oral total).

Estimate. Company shares (all dosage forms, FY2024) are Otsuka Pharmaceutical 37.0%, Janssen Pharmaceutical 22.6% and Sumitomo Pharma 15.9%, in that order. Of Sumitomo Pharma's JPY 16.46 billion, JPY 11.82 billion (71.8%) is lurasidone.

S6 For the four precedent molecules, generics were first listed 1.8–16.8 months after the later of re-examination period expiry and PTE patent expiry

The oral drugs in the same area for which the first generic listing date can be confirmed are four molecules: quetiapine, olanzapine, aripiprazole and blonanserin. One PTE patent was extracted per molecule (Chapter 6).

Key point (listing timing). For all four molecules, generics were listed after the later of expiry of the re-examination period for the first indication and expiry of a PTE patent (one per molecule): 1.8–16.8 months after the later date, and 119–123 days after generic approval (calculated). Aripiprazole also has PTE patent 4178032, which expires after listing. No public document describing the circumstances that determined listing timing was found.

Key point (number of products, NHI price, share). The number of products on the first day was 60, 105, 109 and 32 (consistent with MHLW documents). The NHI price ratio at listing (tablets) was 0.32–0.54, lower than the originator's NHI price multiplied by the rate under the pricing rules at the time (calculated). FY2024 generic volume share was 92.6%, 85.1%, 70.8% and 82.7% (estimate).

Key point (AG). Blonanserin tablets and powder "DSPB" are described as an "authorized generic (AG)" in the company's announcement and interview form, and have the same approval, listing and launch dates as Towa Pharmaceutical's generic. They account for 61.0% of FY2024 generic estimated sales value. For the other 3 molecules, no current generic interview form from any company mentions an AG.

S7 US generics could be marketed from 20 February 2023. North American revenue fell from JPY 198.5 billion to JPY 6.7 billion

Revenue is Sumitomo Pharma's disclosed figure for Latuda in North America (FY2022 → FY2023). We arranged US patent, litigation and generic approval records in date order (Chapter 7).

Key point (US generics). The first final approval of a generic (ANDA) was on 3 January 2019. There are 19 ANDAs with final approval (3 of them listed as discontinued) and 1 with tentative approval. In the FDA NDC Directory, 16 of the 20 ANDAs have products listed. US generics include a 120mg tablet, which does not exist in Japan.

Key point (revenue and price). Sumitomo Pharma's North American Latuda revenue went from JPY 198.5 billion in FY2022 to JPY 6.7 billion in FY2023 (down 96.6%; the company's forecast for FY2024 was JPY 5.4 billion). According to a US FDA estimate, the price per tablet went from $43 to $0.80 after 12 months (a 98% decline).

Key point (Europe). In Europe, supplementary protection certificates (SPCs) are registered until 26 March 2029 in the Netherlands and until 27 March 2029 in Luxembourg. Generics are not listed among EMA centralized authorizations and are authorized nationally. Generics appear in the official lists of the Netherlands, the UK and Spain (launch dates not confirmed).

S8 FY2024 volume × April 2026 NHI price = JPY 11.23 billion. Calculation tables apply pricing-rule rates and volume shares

The two tables on page 13 of the Japanese original are calculated by multiplying the April 2026 NHI price and FY2024 volume by the rates under current pricing rules and by assumed volume shares (Chapter 4).

Estimate. By strength in FY2024, 20mg accounts for 68.7% of tablets, 51.3% of estimated sales value and 47.9% of API-equivalent quantity. 60mg and 80mg together account for 8.5% of tablets and 20.3% of API-equivalent quantity.

Calculation. FY2024 volume multiplied by the April 2026 NHI price gives JPY 11.23 billion. The table values are this figure multiplied by the rates and volume shares.

Regulatory rule. Generic pricing rules are set out in Chapter 4 and application and listing timing rules in Chapter 3, based on the original texts. See the notes for the handling of individual products and Appendix D for items not confirmed.

S9 Outlook (estimate): pre-entry market size of JPY 15.12 billion in FY2030. With first listing in December 2031, first-year generic sales of JPY 2.57 billion

Using the facts in Chapters 1–9 and precedents in our database, we estimated the market and generic entry for FY2025–FY2036 (Chapter 10). Values are the central case (each assumption set to its middle value), with the 10th–90th percentile in parentheses; values are on an NHI price basis and include public expenditure.

Estimate. FY2025 volume (excluding public expenditure) is +6.7% vs FY2024 (+0.9% to +13.0%). Market size plateaus in FY2027–FY2030, with a range of JPY 8.59–20.32 billion in FY2030.

Estimate. In year 1 of S1 (FY2032), generic volume is 41.9 million tablets (49.5% volume share) and the total market is JPY 8.39 billion. Applying the precedent distribution, the leading company has JPY 1.18 billion, an even split among 7 companies gives JPY 0.37 billion each, and the API-equivalent quantity for all generics is 1,203 kg.

Key point. S1 assumes the PTE patents do not block approval or listing. If they do, first-year generic sales are JPY 2.62 billion under S3 (December 2032) and JPY 2.43 billion under S4 (December 2035). The S1 application falls in the March–August 2030 round.

Original pages (Japanese)

The executive summary as published in the Japanese original, reduced in size. Each page has a headline, key points, then figures and tables with sources.



再審査期間満了は2030年3月24日。2024年度の推計額は118.2億円、後発品の薬価収載なし

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再審査期間は2030年3月24日まで。延長登録のある8特許は2028年8月～2035年10月に満了

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延長登録のある8特許に無効審判・訴訟の記録なし。請求の範囲に「ルラシドン」を含む他社公報は130件

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2024年度の推計額は118.2億円。同一条件での伸び率は +22.9%、+12.5%で、数量増による

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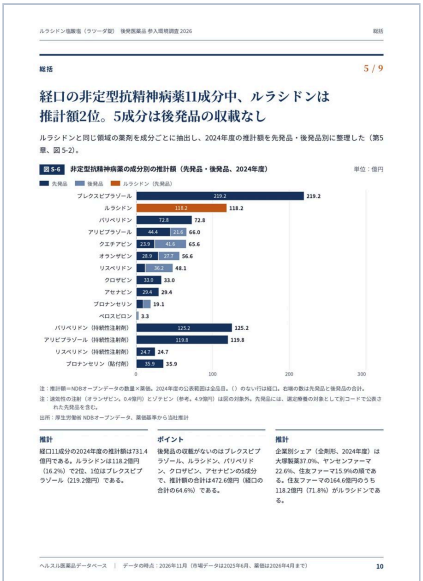

経口の非定型抗精神病薬11成分中、ルラシドンは推計額2位。5成分は後発品の収載なし

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先行4成分の後発品の初回収載は、再審査期間と延長登録のある特許の満了の遅い方から1.8～16.8か月後

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ルラシドン塩酸塩（ラツーダ錠） 後発医薬品 参入局特調査 2026 総括

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米国の後発品の販売可能日は2023年2月20日。北米の売上収益は1,985億円から67億円に減少

売上収益は、住友ファーマが開示する北米のラツーダの値（2022年度→2023年度）である。米国の特許・訴訟・後発品の承認の記録を、日付順に整理した（第7章、図7-1）。

図 5-10 米国の年表：特許の満了日、訴訟、後発品の承認と販売が可能とされた日（2010～2032年）

注：物質特許 5,532,372 と用途特許 9,815,827 の満了日と小売の延長は、オレンジブックの過去のデータファイル（現行の版には掲載なし）。製剤特許と用途特許（2本）の満了日と小売の延長はオレンジブック（2026-10-09 版）。小売の延長の付が為るのは、製剤特許4本のうち3本、用途特許2本のうち1本、等の効まりは登録日（製剤特許は 8,729,085、用途特許2本は 9,259,423 の登録日。ほかの特許の登録日は未確認）。

注：提訴の日は訴訟の日付（2018-02-13 に1法人、2018-02-23 に16法人）。販売が可能とされた日は訂正後の日付。縦の実線は本書の作成日。

出所：FDA Orange Book（2026-10-09 版と過去のデータファイル）、openFDA drugs&ba、Google Patents、米国特許 9,815,827 の公報、Sunovion の発表（2015-01-14）、ニュージャージー州連邦地域の事件の記録（CourtLaunner）、住友ファーマの発表（2018-11-27、2018-12-28 訂正）、米国連邦巡回区控訴裁判所 No. 2022-2276（2024-04-05）から当社作成

ポイント（米国の後発品）
最初の後発品（ANDA）の最終承認は2019年1月3日である。最終承認のANDA は19件（うち3件は販売中止の掲載）、暫定承認は1件である。FDA のNDC ディレクトリには、ANDA 20件のうち16件に製品の登録がある。米国の後発品には、日本にない120mg の錠がある。

ポイント（売上・価格）
住友ファーマの北米のラツーダの売上収益は、2022年度 1,985億円から2023年度 67億円になった（△96.6%、2024年度の企業の予想は 54億円）。米国FDA の推計では、1錠の価格は $43 から12か月後に $0.80 になった（98%の下落）。

ポイント（欧州）
欧州では補充的保護証明書（SPC）がオランダで2029年3月26日まで、ルクセンブルクで2029年3月27日まで登録されている。後発品は EMA の中央承認の一覧に掲載がなく、各国の承認である。オランダ・英国・スペインの公的な一覧に後発品の掲載がある（発売日は未確認）。

ヘルスル医薬品データベース ｜ データの時点：2026年11月（市場データは2025年4月、薬価は2024年4月まで） 12

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ルラシドン塩酸塩（ラツーダ錠） 後発医薬品 参入局特調査 2026 総括

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2024年度の数量×2026年4月の薬価は112.3億円。算定ルール上の率と数量シェアを乗じた値を計算表で示す

下の2表は、2026年4月の薬価と2024年度の数量に、現行の算定ルール上の率と、仮定した数量シェアを乗じた計算値である（第4章、表 4-9）。

表 5-3 2026年4月の薬価に算定ルール上の率を乗じた値と、2024年度の数量×2026年4月の薬価の金額（計算）

規格	2026年4月の薬価（円/錠）	×1005分の50（円）	×1005分の40（円）	×1（円）	2024年度の数量（万錠）	数量×2026年4月の薬価（億円）
20mg	154.6	77.30	61.84	154.6	3,722.7	57.55
40mg	288.1	144.05	115.24	288.1	1,236.5	35.62
60mg	408.8	204.40	163.52	408.8	255.1	10.43
80mg	428.2	214.10	171.28	428.2	203.3	8.70
合計					5,417.6	112.31

注：率を乗じた値＝2026年4月1日の薬価×0.5、×0.4、×1（円。複数処理と規格間調整は未反映）。率は「薬価算定の基準について」（2026年4月1日から適用）の規定の数値で、「×1」は、先発品と同一の後発品（率を乗じる規定がない）をとと仮定した。

注：金額＝2024年度の数量（NDBオープンデータ）×2026年4月1日の薬価。

出所：厚生労働省 通知「薬価算定の基準について」（保険2212第1号、2026-02-13）、NDBオープンデータ（2024年度）、薬価基準（2026年4月1日適用）から当社作成

表 5-4 数量シェアと薬価の比を仮定したときの金額（2024年度の数量、2026年4月の薬価、計算） 単位：億円

仮定した数量シェア	数量（万錠）	原薬換算量（kg）	薬価の比 0.5（億円）	薬価の比 0.4（億円）	薬価の比 0.3（仮定値、億円）
10%	541.8	155.5	5.6	4.5	3.4
30%	1,625.3	466.5	16.8	13.5	10.1
50%	2,708.8	777.4	28.1	22.5	16.8
70%	3,792.3	1,088.4	39.3	31.4	23.6
90%	4,875.9	1,399.4	50.5	40.4	30.3

注：金額＝112.3億円×数量シェア×薬価の比（0.5・0.4は算定ルール上の率と同じ数値、0.3は算定ルール外の仮定値）。

注：数量は NDBオープンデータの公表値。数量の伸び、今後の薬価改定、規格間調整は未反映。数量の伸び・薬価改定・シェアの曲線を入れた推計は第10章 10.7章。

出所：厚生労働省 NDBオープンデータ（2024年度）、薬価基準（2026年4月1日適用）から当社作成

推計
2024年度の規格別では、20mg が錠数の68.7%、推計額の51.3%、原薬換算量の47.9%を占める。60mg と 80mg は錠数で合計6.5%、原薬換算量で20.3%である。

計算
2024年度の数量に2026年4月の薬価を乗じると 112.3億円になる。表の値は、これに率と数量シェアを乗じた計算値である。

制度上のルール
後発品の薬価算定ルールは第4章（4.6節）、申請・収載時期のルールは第3章（3.10節）に、原文に基づいて整理した。個別品目の取扱いは留意事項、未確認事項は資料D を参照。

ヘルスル医薬品データベース ｜ データの時点：2026年11月（市場データは2025年4月、薬価は2024年4月まで） 13

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ルラシドン塩酸塩（ラツーダ錠） 後発医薬品 参入局特調査 2026 総括

総括 9 / 9

見通し（推計）：参入前の市場規模は2030年度151.2億円。2031年12月の初回収載なら、1年目の後発品は25.7億円

第1～9章の事実と当社データベースの先例から、2025～2036年度の市場と後発品の参入を推計した（第10章）。値は中心の場合（各仮定を中の値に置いた計算）、括弧内は10%点～90%点、金額は薬価ベース・公費を含む。

図 5-11 見通しの主要な数字（推計）

注：市場規模＝数量（公費を含む）×薬価、51＝後発品の初回収載を2031年12月と仮定した場合。薬号数は内用・参入前年度100億円以上・2021年度以降に参入した先例。

出所：厚生労働省 NDBオープンデータ（年度・月次公開第12回）、薬価基準、当社データベース（新薬・後発品の先例）から当社推計

図 5-12 市場規模の見通し（2025～2036年度、51、推計） 単位：億円

注：低・高は10%点・90%点。2031年度以降は後発品を含む市場全体。

出所：厚生労働省 NDBオープンデータ、薬価基準、当社データベースから当社推計

推計
2025年度の数量（公費を除く）は2024年度比 +6.7%（+0.9～+13.0%）。市場規模は2027～2030年度に頭打ちとなり、2030年度は85.9～203.2億円の幅がある。

推計
51 の1年目（2032年度）は、後発品の数量4,190万錠（数量シェア49.5%）。市場全体83.9億円。先例の分布を当てると、1位の企業は11.8億円、7社で等分すると3.7億円。原薬換算量は後発品全体で1,203kg。

ポイント
51 は延長登録のある特許が承認・収載を拒げない場合。欧げる場合の1年目の後発品は 53（2032年12月）26.2億円、54（2035年12月）24.3億円（表 10-3）。51 の申請は2010年3～4月の期にあたる。

ヘルスル医薬品データベース ｜ データの時点：2026年11月（市場データは2025年4月、薬価は2024年4月まで） 14

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