

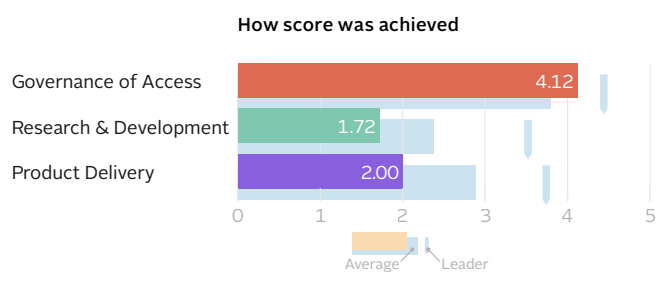
RANK	SCORE
<b>15</b>	<b>2.23</b>
16 (2022)	

# Astellas Pharma Inc

Stock exchange: TSE • Ticker: 4503 • HQ: Tokyo, Japan • Employees: 14,754

## PERFORMANCE IN THE 2024 INDEX

**15<sup>th</sup> place.** Astellas performs below average. It performs above average in Governance of Access but has a comparatively poor performance in Research & Development and Product Delivery, where the geographic scope of its access plans and strategies is limited.



### OPPORTUNITIES FOR ASTELLAS

**Improve the quality and broaden the geographic reach of access plans.** Currently, Astellas has access plans for 66% of its late-stage candidates in the pipeline. The depth and geographic coverage of access plans are limited, primarily focusing on supply and demand plans that include three countries in scope, on average. The company can expand its plans, for example, by including equitable pricing and/or licensing and broadening the geographic coverage of these plans to focus more on low- and middle-income countries.

**Expand access to innovative oncology medicines.** Astellas has access strategies in place for its innovative oncology medicines, but these are limited in geographic reach, with no low-income country currently covered. It can increase access to these products, such as enfortumab (Padcev®), indicated for bladder cancer, and gilteritinib (Xospata®), indicated for leukaemia, through increased registration, equitable access strategies and/or licensing, with a particular focus on countries with the highest burden of disease.

**Establish direct board-level responsibility for access to medicine.** Astellas has an access-to-medicine strategy. The Sustainability Committee, responsible for this strategy, reports to the CEO. To further progress, the CEO can become a member of the Sustainability Committee, elevating the responsibility for the access-to-medicine strategy to board level.

### CHANGES SINCE THE 2022 INDEX

- The Astellas Global Health Foundation announced new grants totaling USD 3.9 million in December 2022 to five organisations in the Dominican Republic, El Salvador, Guinea-Bissau, Honduras, Kenya, Senegal and Uganda. Additionally, in January 2024, it awarded USD 2.6 million to three organisations in Kenya, Yemen and Peru. These grants focus on improving access to healthcare, disaster relief and enhancing community resilience.
- In January 2023, Astellas transferred the worldwide product rights for micafungin (Mycamine®) to Sandoz AG.
- In December 2023, Astellas completed the acquisition of Propella Therapeutics, adding PRL-02 (abiraterone decanoate) for the treatment of prostate cancer to its clinical pipeline.
- In December 2023, the European Medicines Agency adopted a positive scientific opinion for a paediatric formulation of arpraziquantel for the treatment of schistosomiasis in preschool-aged children (3 months to 6 years of age). Astellas contributed to the development as a member of the Pediatric Praziquantel Consortium.

# Astellas Pharma Inc

## SALES AND OPERATIONS

**Therapeutic areas:** Oncology, nephrology, transplantation, urology

**Product categories:** Innovative medicines

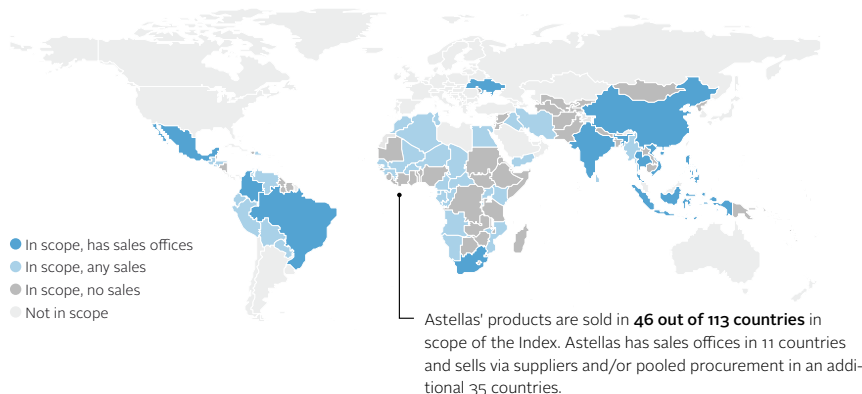
**M&A news:** Astellas reacquired its shares at a total value of YEN 50bn in 2023. In 2023, Astellas acquired IVERIC Bio, Inc. for USD 5.9bn

and Propella Therapeutics for USD 175mn, respectively.

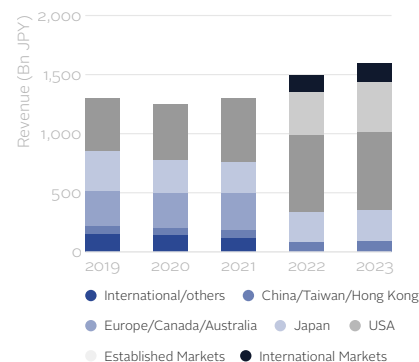
### Revenue by segment (2023) – in JPY

Pharmaceutical	1,603.67 bn
<b>Total</b>	<b>1,603.67 bn</b>

### Sales in countries in scope



### Sales by geographic region



## SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

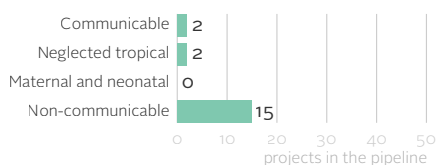
### PIPELINE for diseases in scope

Astellas has 19 R&D projects in scope, 4 of which target priority diseases, including Chagas disease (1), leishmaniasis (1) and schistosomiasis (1). The remaining 15 projects target other diseases in scope, including cancer (14) and kidney disease (1). Of the 19 R&D projects, 6 are in late-stage development, with evidence of access planning for 67% (4/6) of these.

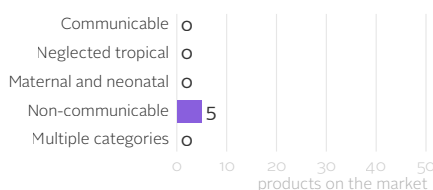
### PORTFOLIO as selected for analysis by the Index

Astellas has 5 medicines in scope, 1 of which is listed on the WHO EML. All its medicines are on patent and exclusively target non-communicable diseases, such as cancer (4) and kidney diseases (1).

### 19 projects in the pipeline



### 5 products in the portfolio



### Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	3	0	0	0	0	0	1	0	4
with access plan			0	0	0	0	1		1
Other projects in scope		10	1	2	0	2	0		15
with access plan			1	0	0	2			3

### Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	1	4			5
off patent	0	0			0
Vaccines	0	0			0
Contraceptives	0	0			0
Diagnostics			0		0
Other				0	0

# Astellas Pharma Inc

## GOVERNANCE OF ACCESS

RANK 8

SCORE 4.12

**8<sup>th</sup> place.** Astellas performs above average in this Technical Area. Although the company does not have direct board-level responsibility for access to medicine, it has a comprehensive access-to-medicine strategy integrated within its overall corporate strategy. Further, Astellas has a robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities.

**The highest responsibility for access lies indirectly with the Board, with the Sustainability Committee overseeing social activities, including access.** Astellas has access-related incentives at both the executive and in-country manager levels. The CEO also has access-related incentives linked to their remuneration plan.

**Comprehensive access-to-medicine strategy integrated within the overall corporate strategy.** Its strategy covers all therapeutic areas in which the company is involved. Astellas publicly discloses its commitments to access to medicine, along with company-specific measurable targets, goals and objectives. Reporting is clear, linked to these goals, centrally available and updated regularly in its Integrated Report.

**Shows comparatively strong commitment to responsible business practices.** Astellas sets team-level sales targets when individual-level targets are not possible, and incentives are

not solely based on sales volume. It commits to ensuring ethical interactions with healthcare professionals in its code of conduct. It also offers guidance on establishing and documenting a legitimate need for interaction and declares that transfers of value to healthcare professionals (e.g., payments for attending events or for promotional activities) are made at fair market value. However, it only publicly discloses information on such payments in countries in scope if required by law or local regulation.

**Has robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities.** Astellas performs strongly in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance with company standards, fraud-specific risk assessments and region or country risk-based assessments. Astellas also has an ethical decision-making framework for employees. No

breaches in countries in scope were found in the period of analysis.

**Astellas publicly supports the Doha Declaration on TRIPS and Public Health.** However, it expresses reservations on some provisions of TRIPS flexibilities, namely compulsory licensing. Astellas states that compulsory licensing is justified only in national emergencies or other urgent situations, in line with international regulations, and only after exhausting all other options.

**Fulfils some criteria across 2 processes for measuring and reporting patient reach.** For 1 process covering all its products and some countries in scope of the Index, Astellas publicly provides the metrics. The resulting patient reach numbers are published regularly and demonstrate improvements. The process also has a measurable patient reach goal but no associated health outcomes goal was identified.

## RESEARCH & DEVELOPMENT

RANK 16

SCORE 1.72

**16<sup>th</sup> place.** Astellas has a below-average performance in this Technical Area. It has a small-sized pipeline compared to its peers and engages in R&D for priority diseases and non-communicable diseases. The company has an access planning framework, and it has access plans for most late-stage pipeline candidates – although the breadth and depth of plans are limited. Astellas does not publicly disclose disaggregated R&D investment data, nor does it engage in R&D capacity building activities.

**Structured process in place to develop access plans during R&D.** The process is intended to be applied to all R&D projects in scope. The company does not make a public commitment addressing its systematic approach to access planning for LMICs.

**Small-sized priority R&D pipeline, compared to peers, with access plans in place for 100% (1/1) of the late-stage candidates.** Priority R&D pipeline of 4 projects, including 1 late-stage project targeting a priority gap. The company focuses on various priority areas, including Chagas disease, leishmaniasis and schistosomiasis. Astellas' 1 late-stage candidate targeting a priority product gap has evidence of an access plan, including

multiple components, such as WHO prequalification, a technology transfer agreement and equitable pricing plans.

**Small-sized pipeline compared to peers, that addresses other diseases in scope, with 60% (3/5) of late-stage projects covered by access plans.** The company has 5 late-stage R&D projects targeting diseases in scope that have not been established as a priority by global health stakeholders. The projects target cancer and kidney disease. Astellas provides evidence of access plans for 3 of its 5 late-stage projects. Access plans include supply and demand plans, registration preparation and post-trial access in countries in scope.

**Astellas does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development.** Furthermore, it does not disclose disaggregated R&D investment data to global health organisations.

**No evidence of R&D capacity building initiatives that meet inclusion criteria.**

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## PRODUCT DELIVERY

RANK 16

SCORE 2.00

**16<sup>th</sup> place.** Astellas performs below average in this Technical Area. The company shows no evidence of manufacturing capacity building initiatives or of new intellectual property sharing agreements. It has access strategies in place for its products; however, geographic reach and outcomes data is limited. Astellas engages in a supply chain capacity building initiative, but it does not meet Good Practice Standards (GPS). Astellas does engage in some health system strengthening initiatives that meet all GPS.

**Astellas registers products in 16 countries in scope on average.** For the 1 newer product\* analysed, it registers in 7 countries in scope. All products assessed are registered in at least 1 of the 10 countries with the highest disease burden; however, no products are registered in any LICs. The company's enzalutamide (Xtandi™), indicated for prostate cancer, is most widely registered, totalling 29 countries in scope. Astellas participates in regulatory reliance to facilitate registration for 1 of its products.

**Astellas is not eligible for assessment of supranational access strategies because it has no products in scope that are supranationally procured.**

**One healthcare practitioner (HCP)-administered product, with limited access strategy and outcomes data.** For its HCP-administered product indicated for bladder cancer, the company provides evidence of access strategies in UMIC and LMIC examples. Astellas' access strategy is in the private sector only, with plans to expand to the public sector. There are no plans to launch it in LICs. Astellas provides evidence of engaging in health system strengthening, focused on HCP training in an LMIC. The company provides some information regarding the methodologies used to monitor the outcomes of the strategy but does not disclose the number of patients reached.

**Quality of access strategies for self-administered products varies across countries, with limited information reported on the outcomes of most strategies.** Astellas provides examples of access strategies in UMICs and LMICs, but none in LICs, for the 2 products analysed. For one of its products, the company has a comprehensive access strategy in Mexico (UMIC) where the product is fully reimbursed by the public health system. The strategy is supported by additional strategies, such as a patient support programme and a model to shorten distribution time. The same quality is not found in the access strategies for the LMIC example for the same product, nor for the second product assessed. However, for these strategies, Astellas reports goals to expand access in the public sector. The company reports patient reach data and evidence of an increase only for the strategy in Mexico.

**Astellas publicly commits not to file for or enforce patents for all products in a subset of countries in scope.** This commitment applies to least developed countries and LICs.

**Publicly discloses product patent status for countries in scope.** Like most peers, Astellas publicly discloses patent information for small molecules in scope via the Pat-INFORMED database, including information such as filing date, grant number, grant date and jurisdiction.

**Astellas does not engage in non-exclusive voluntary licensing for products in scope.**

**No evidence of manufacturing capacity building initiatives that meet inclusion criteria.**

**One supply chain capacity building initiative was included for analysis but it does not meet all Good Practice Standards (GPS).** In this initiative, Astellas partners with PATH in Kenya to support integrated HIV and TB care. This includes conducting a supply chain assessment for contraceptive/HIV prevention supplies and designing solutions to improve their availability in health centres.

**Three of the four health system strengthening initiatives included for analysis meet all GPS.** For example, The Astellas Global Health Foundation granted funds to Amref Health Africa to train health workers and improve paediatric care in 2 under-resourced regions in Senegal.

**Astellas remains engaged in existing IP-sharing agreements with public research institutions and drug discovery initiatives to accelerate drug development.** In a 2021 agreement, the company shared 20,000 compounds with the TB Alliance to screen against mycobacterium TB. However, Astellas has not made new agreements during the period of analysis.

**Fulfils most criteria for ad hoc donations.** Astellas has policies and supply processes to carry out ad hoc donations rapidly in response to expressed need, with delivery monitored to ensure donations reach patients. However, the company does not make public commitments to adhere to the most recent WHO Guidelines for Medicine Donations.

**Fulfils most criteria for mechanisms to ensure continuous supply in LMICs.** For example, Astellas manages buffer stocks in countries with their own warehouses. Where there are no warehouses, Astellas supports third parties to hold sufficient stocks. However, the company lacks mechanisms, such as engaging in technology transfer agreements.

**Astellas has a policy for reporting substandard and falsified medicines in countries in scope.** It reports cases to both WHO Rapid Alert and/or national or local regulatory authorities within 10 business days. The company provides evidence of shortened timeframes for reporting for cases that only require visual inspection by experts for confirmation and are not contingent upon laboratory analysis.

**No evidence of inclusive business models that meet inclusion criteria.** However, Astellas engages in initiative(s) that address access needs of neglected populations. For example, Astellas is offering one of its oncology products to low-income populations through a patient assistance programme in India.

\*Products that received their first marketing authorisation within the last 5 years.