

MEDIA RELEASE

Sandoz enters global collaboration license agreement with Henlius to commercialize leading oncology therapy, ipilimumab, in multiple indications

- Agreement offers rights to commercialize proposed biosimilar of Yervoy®* for treatment of variety of cancer types, targeting net reference medicine sales of USD 2.5 billion[1]
- Henlius to develop and manufacture biosimilar, with Sandoz to register and commercialize after expiry of relevant patents across global markets
- Combination therapy of ipilimumab and nivolumab used in 95% of eligible patients[2]; ipilimumab highly complementary to proposed Sandoz nivolumab biosimilar
- Potential to address considerable unmet medical needs and increase worldwide access; reinforces Sandoz commitment to expand patient access and drive sustainable savings for healthcare systems

Basel, April 29, 2025 – Sandoz (SIX:SDZ/OTCQX:SDZNY), the global leader in generic and biosimilar medicines, announced today that it has signed a global collaboration agreement with Shanghai Henlius Biotech, Inc. (Henlius, HKEX:02696) to commercialize a biosimilar of leading oncology therapy, ipilimumab. The agreement is milestone-based for a total consideration of up to USD 301 million, including an upfront payment of USD 31 million, and will target net reference-medicine sales of USD 2.5 billion[1].

Under the terms of the agreement, Sandoz has exclusive commercial rights for a biosimilar of ipilimumab in Australia, Canada, Europe, Japan and the US. The core sequence patent for ipilimumab expired in March 2025 in the US and will expire no later than February 2026 in the EU.

Richard Saynor, CEO of Sandoz, said: “The global burden of cancer continues to grow and the potential to address unmet patient needs has never been greater.[3] This agreement offers us the chance to reach many more millions of patients, while helping to drive the long-term sustainability of healthcare systems.”

The reference medicine, ipilimumab, is a monoclonal (CTLA-4) antibody-blocking medication, which is used alone or with other medicines to treat certain types of colorectal cancer, esophageal cancer, hepatocellular carcinoma (a type of liver cancer), malignant pleural mesothelioma, melanoma, non-small cell lung cancer, and renal cell carcinoma (a type of kidney cancer).[4,5,6]

Henlius is developing its own proposed biosimilar of ipilimumab in an integrated Phase I/III trial in the unresectable hepatocellular carcinoma setting, targeting 656 patients to be enrolled (NCT06841185).

Sandoz is developing its own proposed biosimilar of nivolumab in an integrated Phase I/III trial in the advanced melanoma setting, targeting 720 patients to be enrolled (NCT06587451). The reference medicine, nivolumab, (Opdivo®**) is a monoclonal (PD-1) antibody-blocking medication, which is used alone or with

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other medicines to treat more than 10 different cancer types. In combination with ipilimumab, nivolumab is indicated for the treatment of melanoma, malignant pleural mesothelioma, renal cell carcinoma, certain types of colorectal cancer, esophageal cancer, non-small cell lung cancer and hepatocellular carcinoma.[7,8]

Sandoz is the leading biosimilar provider globally and has recently moved up to third position in the US, with a strategic ambition to occupy the leading position in that market.[9] The Company's industry-leading biosimilars pipeline comprises 28 molecules, complemented by around 450 generic pipeline medicines to support its goal of sustainable and broadly-based long-term growth. The marketed biosimilar oncology portfolio includes Rixathon®, Zarzio®, Ziextenzo®, and Binocrit®. This year, Sandoz expects to launch its biosimilars Wyost®/Jubbonti® (denosumab) in the US in the second quarter and in Europe in the fourth quarter.

* Yervoy® is a registered trademark of Bristol-Myers Squibb (US)

** Opdivo® is a registered trademark of Bristol-Myers Squibb (US)

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REFERENCES

1. Loss-of-exclusivity (LoE) dates based on IP databases; originator-sales data at LoE-1 from internal analysis and *Evaluate Pharma* [November 2024]
2. Decisions Resource Group (DRG) database of total treated population with Yervoy® (G7 markets) [accessed April 2025]
3. [Cancer Today](#) [accessed March 2025]
4. [Yervoy® US Prescribing Information](#) [accessed March 2025]
5. [Yervoy® EMEA Summary of Product Characteristics](#) [accessed March 2025]
6. [Definition of Yervoy® - NCI Dictionary of Cancer Terms - NCI](#) [accessed March 2025]
7. [Opdivo® US: Prescribing Information](#) [accessed March 2025]
8. [Opdivo® EMEA Summary of Product Characteristics](#) [accessed March 2025]
9. IQVIA [download February 2025]

ABOUT SANDOZ

Sandoz (SIX: SDZ; OTCQX: SDZNY) is the global leader in generic and biosimilar medicines, with a growth strategy driven by its Purpose: pioneering access for patients. More than 20,000 people of 100 nationalities work together to ensure 900 million patient treatments are provided by Sandoz, generating substantial global healthcare savings and an even larger social impact. Its leading portfolio of approximately 1,300 products addresses diseases from the common cold to cancer. Headquartered in Basel, Switzerland, Sandoz traces its heritage back to 1886. Its history of breakthroughs includes Calcium Sandoz in 1929, the world's first oral penicillin in 1951, and the world's first biosimilar in 2006. In 2024, Sandoz recorded net sales of USD 10.4 billion.

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