Press Release

Astellas Enters Agreement with Bristol Myers Squibb to Acquire Commercialization Rights in Japan for Onureg® Approved as Maintenance Therapy for Acute Myeloid Leukemia

- Bringing a New Treatment Option to Patients with Acute Myeloid Leukemia in Japan -

TOKYO, November 24, 2026 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") today announced that it has entered into an agreement with Celgene International Sàrl, a subsidiary of the global biopharmaceutical company Bristol Myers Squibb ("BMS") to acquire the rights to commercialize Onureg® (azacitidine tablets), which has been approved as a maintenance therapy for acute myeloid leukemia (AML), in Japan. Under the terms of the agreement, Astellas will obtain the rights to commercialize Onureg® in Japan. BMS will retain exclusive rights to develop and commercialize Onureg® in the rest of the world.

AML is an aggressive blood cancer characterized by the uncontrolled proliferation of abnormal leukemic cells in the bone marrow and is associated with an increased incidence in older populations[1,2]. There are approximately 6,000 patients with AML in Japan[3,4]. Treatment options in Japan remain limited for patients who are not candidates for hematopoietic stem cell transplantation following intensive induction chemotherapy, representing a significant unmet medical need.

Onureg® is a once-daily oral hypomethylating agent developed to maintain remission in adult patients with AML. In the pivotal Phase 3 QUAZAR® AML-001 trial conducted by BMS, Onureg® demonstrated statistically significant improvements in both overall survival (OS) and relapse-free survival (RFS) compared with placebo[5].

Claus Zieler, Chief Commercial & Medical Affairs Officer, Astellas
"Astellas is committed to creating and delivering greater VALUE faster for patients through both internal innovation and strategic partnerships. Onureg® has the potential to become an important new maintenance treatment option for AML patients who do not proceed to stem cell transplantation after achieving remission. By adding Onureg® to our portfolio in Japan, we further strengthen our AML franchise and expand our capability to bring meaningful treatment options to more patients living with AML."

The impact of this matter on Astellas' financial results for the fiscal year ending March 31, 2027, is expected to be minor.

About Acute Myeloid Leukemia (AML)

Acute myeloid leukemia (AML) is one of the most common forms of acute leukemia in adults. There are approximately 6,000 patients with AML in Japan[3,4]. AML develops when immature blood-forming cells in the bone marrow become cancerous and proliferate abnormally, resulting in reduced production of normal blood cells. This can lead to symptoms such as anemia, bleeding, fever, headache, joint pain and increased susceptibility to infections[6]. AML is a rapidly progressing disease that requires prompt diagnosis and treatment[6]. Even after remission is achieved, relapse remains common, and additional treatment options are needed to maintain remission and improve long-term outcomes in patients who are not eligible for hematopoietic stem cell transplantation[7].

About Onureg®

Onureg® is a once-daily oral DNA methylation inhibitor that is incorporated into both DNA and RNA. Its primary mechanisms of action are believed to include DNA hypomethylation and direct cytotoxicity against abnormal hematopoietic cells in the bone marrow. DNA hypomethylation may restore the normal function of genes involved in cellular differentiation and proliferation[8,9].

Onureg® is approved in the United States and Europe as a continued treatment for adult patients with AML who achieved first complete remission (CR) or complete remission with incomplete hematologic recovery (CRi) following intensive induction chemotherapy but are unable to complete intensive consolidation therapy. It is also approved in Canada as maintenance therapy for adult AML patients who achieve CR or CRi after induction therapy, with or without consolidation therapy, and who are not candidates for hematopoietic stem cell transplantation. In Japan, Onureg® received marketing approval in August 2026 for maintenance therapy in AML.

About Astellas

Astellas is a global life sciences company committed to turning innovative science into VALUE for patients. We provide transformative therapies in disease areas that include oncology, ophthalmology, urology, immunology and women's health. Through our research and development programs, we are pioneering new healthcare solutions for diseases with high unmet medical need. Learn more at www.astellas.com.

Cautionary Notes

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management’s current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas’ intellectual property rights by third parties. Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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Contacts for inquiries or additional information:

Astellas Pharma Inc.
Corporate Communications
+81-3-3244-3201

References:

1. American Cancer Society. What Is Acute Myeloid Leukemia (AML)? Available at: What Is Acute Myeloid Leukemia (AML)? | American Cancer Society | American Cancer Society Last accessed January 23, 2023.
2. American Cancer Society. Key Statistics for Acute Myeloid Leukemia (AML). Available at: Key Statistics for Acute Myeloid Leukemia (AML) | American Cancer SocietyLast accessed January 23, 2023.
3. 国立がんセンター　がん統計 白血病
4. 日本内科学会雑誌第113巻第7号、1225-1234
5. https://www.bms.com/jp/media/press-release-listing/press-release-listing-2021/20210726.html
6. https://ganjoho.jp/public/cancer/AML/index.html
7. https://www.jshem.or.jp/gui-hemali/1_1.html
8. Laille et al. PLoS One. 2015;10(8):e0135520
9. Garcia-Manero et al. J Clin Oncol. 2011;29(18):2521–7