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MPP Strikes Landmark Licensing Deal With Novartis On Nilotinib

Agreement On Tasigna Generics Represents First Such Deal For A Cancer Medicine

by David Wallace

The Medicines Patent Pool has struck a milestone voluntary licensing deal with new partner Novartis for nilotinib to treat chronic myeloid leukemia, representing the first MPP agreement in non-communicable diseases as well as the "first ever public health-oriented voluntary license agreement on a cancer medicine."

A milestone voluntary licensing agreement has been struck between the Medicines Patent Pool and new partner Novartis for nilotinib to treat chronic myeloid leukemia (CML) in seven middle-income countries. The product will be marketed by the originator under the Tasigna brand name.

Under the terms of the agreement, selected generic manufacturers will be able to develop, manufacture and supply generic versions of nilotinib in the licensed territory, subject to local regulatory authorization.

The MPP is now *inviting expressions of interest* from potential sublicensees for sublicences to manufacture and sell nilotinib in the licensed territory, which "includes seven middle-income countries, namely Egypt, Guatemala, Indonesia, Morocco, Pakistan, the Philippines and Tunisia, where patents on the product are pending or in force." The deadline for applying is 18 December 2022.

The deal represents the first MPP agreement in non-communicable diseases, with the MPP noting that it is also "the first licence that MPP has signed for a cancer treatment, and the first time a company is licensing a patented cancer medicine through a public health-oriented voluntary licensing mechanism."

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Nilotinib is a twice-daily oral medication used to treat CML. Since 2017 it has been included on the World Health Organization's model list of essential medicines for treatment in adults – and since 2019 for children of at least one year of age – as second-line therapy for the treatment of chronic myeloid leukemia that is resistant to imatinib.

Announced on the sidelines of the World Cancer Congress in Geneva today, 20 October, the deal follows the MPP and Novartis both joining the Access to Oncology Medicines (ATOM) Coalition in May this year. (Also see "*Global Cancer Coalition Seeks To Increase Access To Medicines In LLMICs*" - Generics Bulletin, 6 Jun, 2022.)

The ATOM initiative – led by the Union for International Cancer Control – aims at improving access to essential cancer medicines in low- and lower-middle income countries and increasing the capacity for diagnosing cancer and for the proper handling and supply monitoring of these medicines.

Through the MPP, the ATOM Coalition facilitates affordable access to cancer treatments through non-exclusive licences to generic manufacturers for selected products and countries.

LMICs Have Limited Access To New-Generation Oncology Treatments

Highlighting the "tremendous progress in new technologies to treat cancer," the MPP nevertheless pointed out that "major challenges persist in many low- and middle-income countries that face inequity in access to new-generation cancer medicines which could allow patients to live better and longer."

"Advances in treatment, such as nilotinib, have contributed to a greatly improved prognosis for people diagnosed with CML," the MPP underlined.

Charles Gore, executive director of the MPP, emphasized that access to high-quality cancer medicines was a "crucial component of the global health response to the cancer burden," meaning he was "delighted to be signing our first licence agreement with Novartis for a much-needed cancer treatment in LMICs."

"Although the remaining patent life is relatively short," Gore acknowledged, "this voluntary licence in the non-communicable disease space sets a vital precedent that I hope other companies will follow."

Commenting on the deal, Novartis president of global health and sustainability Lutz Hegemann said the firm was "proud to be pioneering this new licensing model with MPP in collaboration with the ATOM Coalition, but we know too that making a medicine available is only one part of the challenge to increase access to cancer treatments. For generic versions of this medicine to reach those who need it, wherever they live, the right diagnostics and quality of care will be

critical."

"That's why we've helped to build the new ATOM Coalition, and we will be relying on the support of our partners from research, non-profits and the private sector to help deliver on the promise of this initiative."

Meanwhile, Benedikt Huttner, secretary of the WHO expert committee on the selection and use of essential medicines, observed that "cancer medicines constitute a large proportion of medicines recommended by WHO on the model lists of essential medicines," with nilotinib "an essential cancer medicine for adults and children with imatinib-resistant CML."

"We welcome this license agreement, the first for cancer medicines," Huttner underlined. "We hope this marks the start of a paradigm shift with more pharmaceutical companies following suit with license agreements for essential patented cancer medicines to help ensure that patients globally can benefit."

The agreement with Novartis adds to recent deal-making momentum for the MPP, including a licensing agreement for Shionogi's oral COVID-19 anti-viral ensitrelvir.

Earlier in the year, the MPP also announced licensees for versions of Merck Sharp & Dohme's molnupiravir (Also see "*Molnupiravir To Reach 105 LMICs Through MPP Agreement*" - Pink Sheet, 21 Jan, 2022.) and Pfizer's Paxlovid (nirmatrelvir and low-dose ritonavir tablets, co-packaged for oral use) COVID-19 antiviral treatment. (Also see "*Coronavirus Notebook: 35 Generic Firms To Produce Pfizer's Paxlovid, AZ's Evusheld Gains UK & Australian Approval*" - Pink Sheet, 17 Mar, 2022.)

Then in August, the MPP secured a further licensing deal with Viiv Healthcare for long-acting injectable cabotegravir for HIV pre-exposure prophylaxis. (Also see "*MPP Strikes Long-Acting Injectable Cabotegravir Deal For HIV PrEP*" - Pink Sheet, 4 Aug, 2022.)