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Positive CHMP Opinion by EMA for Arpraziquantel to Treat Schistosomiasis in Preschool-Aged Children

- **EMA assessed arpraziquantel under the EU-M4all procedure for high-priority medicines intended for use in countries outside the European Union**
- **Merck KGaA, Darmstadt, Germany, is committed to contribute to the elimination of schistosomiasis as a public health problem by 2030**

Darmstadt, Germany, December 15, 2023 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, and the Pediatric Praziquantel Consortium today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive scientific opinion for arpraziquantel for the treatment of schistosomiasis in children aged 3 months to 6 years. The application was submitted by Merck KGaA, Darmstadt, Germany, on behalf of the Consortium, under the EU-M4all procedure for high-priority medicines for human use intended for countries outside the European Union.

"With this positive response by EMA, a critical milestone was achieved to broaden the range of options for the treatment of schistosomiasis so as to address the needs of millions of preschool-aged children", said Peter Guenter, Member of the Executive Board and CEO of Healthcare at Merck KGaA, Darmstadt, Germany. "I thank all partners of the Pediatric Praziquantel Consortium for this achievement and for the

continuous collaboration. Together, we strive to contribute to the elimination of schistosomiasis as a public health problem by 2030, as part of our commitment to drive health equity through our innovations and products."

Arpraziquantel is derived from praziquantel, the standard of care treatment of schistosomiasis developed in the 1970s. Extending the range of options for the treatment of schistosomiasis, arpraziquantel is tailored for use in preschool-aged children. The tablet is administered by dissolving it in water and has an improved taste to make it more palatable for very young children. In addition, the 150mg tablet has been specifically designed to withstand the hot and humid conditions presented by a tropical climate.

The positive CHMP scientific opinion by EMA is the basis for a potential inclusion of arpraziquantel in the World Health Organization's list of prequalified and essential medicinal products. Together with the positive scientific opinion, the planned prequalification will support the regulatory pathway in African countries.

In Brazil, regulatory submission is under preparation by Consortium partner, Farmanguinhos. As the federal governmental pharmaceutical laboratory of the Fiocruz Foundation in Brazil, Farmanguinhos brings expertise in production and distribution, and will be the manufacturing site for the future introduction of the new pediatric medication in endemic countries. For planned future large-scale local production to serve African countries, Merck KGaA, Darmstadt, Germany, has also partnered with Universal Corporation Ltd., Nairobi, Kenya.

In parallel, within the Consortium, the implementation research program (ADOPT) is currently ongoing, preparing for the introduction of arpraziquantel in the first endemic countries in Africa. To support equitable and sustainable access, it is essential that new procurement and funding mechanisms are collaboratively explored and established. The intent is to make the product available at an at-cost basis in sub-Saharan African countries.

The collaborative program on arpraziquantel is part of the integrated approach of Merck KGaA, Darmstadt, Germany, to contribute to the elimination of schistosomiasis as a public health problem. Indeed, through its Schistosomiasis

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Elimination Program, Merck KGaA, Darmstadt, Germany, addresses the key requirements of the WHO's 2021-2030 Roadmap for Neglected Tropical Diseases and contributes to the United Nations' Sustainable Development Goals, especially Good Health and Well-Being (Goal 3) and Partnerships (Goal 17). The program also aligns with the Sustainability Strategy of Merck KGaA, Darmstadt, Germany, and the company's commitment to expand sustainable and equitable access to medicines by bringing its existing products and innovative portfolio to patients in low- and middle-income countries recognizing the needs and the specificity of the health systems in each of the country.

About EU-M4all
Through the EU-M4all procedure, the European Medicines Agency (EMA), in cooperation with the World Health Organization (WHO), can provide scientific opinions on high-priority human medicines, including vaccines, that are intended for markets outside of the European Union (EU). The procedure was previously known as the Article 58 procedure, as the legal basis is Article 58 of Regulation (EC) No 726/2004. More information can be found here.

About Arpraziquantel
The current standard of care treatment for schistosomiasis is praziquantel, listed on WHO's list of essential medicines, and suitable for school-aged children and adults. Extending the range of options for the treatment of schistosomiasis, arpraziquantel is tailored for preschool-aged children against *Schistosoma mansoni* and *Schistosoma haematobium*. Tested in clinical development under the responsibility of Merck KGaA, Darmstadt, Germany, arpraziquantel contains the pharmacologically active enantiomer of praziquantel. It is a 150mg dispersible tablet. The prototype of its pediatric formulation was developed by Astellas in Japan and further optimized by Merck KGaA, Darmstadt, Germany, in Germany. The manufacturing process served to produce clinical trial supplies from Merck KGaA, Darmstadt, Germany, and Farmanguinhos in Brazil. Future manufacturing is planned to be done by Farmanguinhos and Universal Corporation Ltd., in Kenya, which is preparing for extensive local production capacities in and for Africa.

About Schistosomiasis
Schistosomiasis (also known as bilharzia) is one of the most prevalent parasitic diseases worldwide and a very important one in terms of public health burden and economic impact. It is a poverty-related disease that is widespread in tropical and subtropical regions where large sections of the population have no access to clean water. Flatworms transmit the disease and people become infected with the parasite through contact with freshwater, for example, while working, swimming, fishing, or washing their clothes. The minuscule larvae penetrate human skin, enter the blood vessels and attack internal organs. The infection rate is particularly high among children. Schistosomiasis is a chronic condition and is classified by the World Health Organization (WHO) as one of 20 neglected tropical diseases (NTDs).

About the Schistosomiasis Elimination Program of Merck KGaA, Darmstadt, Germany,
Merck KGaA, Darmstadt, Germany, initiated its Schistosomiasis Elimination Program in cooperation with WHO back in 2007. Since then, more than 1.9 billion tablets have been donated, enabling the treatment of over 760 million people, mainly school-aged children in 47 endemic countries. Merck KGaA, Darmstadt, Germany, has committed itself to maintaining its efforts in the fight against the tropical disease until schistosomiasis is eliminated as a public health burden. To this end, each year Merck KGaA, Darmstadt, Germany, provides up to 250 million tablets to WHO. In addition, Merck KGaA, Darmstadt, Germany, has adopted an integrated schistosomiasis strategy that is implemented in close collaboration with partners worldwide and focuses on: treatment, research & development, WASH (Water, Sanitation & Hygiene), advocacy & partnerships. More information about the Schistosomiasis Elimination Program of Merck KGaA, Darmstadt, Germany, is available at www.makingschistory.com.

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About the Pediatric Praziquantel Consortium
The Pediatric Praziquantel Consortium is an international not-for-profit partnership that aims to help improving child's health by addressing the medical needs of preschool-age children with schistosomiasis for potentially reducing the global burden caused by this disease. Its mission is to develop, register and provide access to a suitable pediatric drug for treating schistosomiasis in children three-months to six years of age. For more information, and to see an overview of all Consortium partners, visit the Consortium website: www.pediatricpraziquantelconsortium.org
The Consortium is financially supported by Merck KGaA, Darmstadt, Germany; in-kind contributions from the Consortium's partners; and grants from the Bill and Melinda Gates Foundation (2012), the Global Health Innovative Technology Fund (GHIT) (2014, 2015, 2016, 2019 & 2020), and the European & Developing Countries Clinical Trials Partnership (EDCTP), under its second program supported by the European Union (2018 & 2021).

About Merck KGaA, Darmstadt, Germany
Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across life science, healthcare and electronics. More than 64,000 employees work to make a positive difference to millions of people's lives every day by creating more joyful and sustainable ways to live. From providing products and services that accelerate drug development and manufacturing as well as discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices – the company is everywhere. In 2022, Merck KGaA, Darmstadt, Germany, generated sales of € 22.2 billion in 66 countries.
The company holds the global rights to the name and trademark "Merck" internationally. The only exceptions are the United States and Canada, where the business sectors of Merck KGaA, Darmstadt, Germany, operate as MilliporeSigma in life science, EMD Serono in healthcare and EMD Electronics in electronics. Since its founding in 1668, scientific exploration and responsible entrepreneurship have been key to the company's technological and scientific advances. To this day, the founding family remains the majority owner of the publicly listed company.