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Merck KGaA, Darmstadt, Germany, and Universal Agree on Contract Manufacturing for new Pediatric Medication Against Schistosomiasis

- **Universal to produce new pediatric medication against schistosomiasis on a large scale in Kenya for endemic African countries**
- **The new pediatric drug is currently in clinical Phase III**
- **Collaboration contributes to the sustainability strategy of Merck KGaA, Darmstadt, Germany, and the United Nations' Sustainable Development Goals**

Darmstadt, Germany, July 15, 2021 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, has entered into a contract manufacturing agreement with Universal Corporation Ltd., Nairobi, Kenya, a subsidiary of Strides Pharma Science Limited, India, for the large-scale production of a new pediatric medication. Production will begin once the medication has been registered. The drug is needed to treat the neglected tropical disease (NTD) schistosomiasis in preschool-aged children younger than six and is currently in late-stage development. The agreement with Universal includes building up extensive production capacities in Nairobi, Kenya for future provision of the treatment in endemic African countries. It adds to the manufacturing activities of Farmanguinhos, the federal governmental pharmaceutical laboratory of the Fiocruz Foundation in Brazil, which brings expertise in production and distribution.

“Universal has not only the necessary equipment and knowledge for this kind of production, but also a well-established quality assurance system. That is why we



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really look forward to establishing sustainable supply of the new medication together with our new local partner,” said Teresa Rodó, Head of Global Healthcare Operations at Merck KGaA, Darmstadt, Germany.

“As a group, our strategy has always focused on being in Africa for Africa. We are proud that by establishing local production, we will further support the regional economy and ensure sustainable and equitable access to the new pediatric medication against schistosomiasis for the young patients in need,” said Palu Dhanani, Chief Executive Officer of Universal.

For school-aged children and adults, praziquantel is the standard of care treatment for schistosomiasis. Merck KGaA, Darmstadt, Germany, makes it available by providing the World Health Organization with up to 250 million tablets per year and will continue delivering the treatment until the disease is eliminated. However, the vulnerable group of preschool-aged children has so far been left untreated in public health programs primarily due to the lack of an appropriate child-friendly formulation of the drug. Untreated schistosomiasis can lead to potentially fatal chronic inflammation of vital organs as well as anemia, stunted growth and impaired learning ability, all of which have devastating consequences for the lives of the youngest members of the population.

The new pediatric medication for preschool-aged children, arpraziquantel, is derived from praziquantel. It is smaller and orally dispersible – i.e. it dissolves quickly in the mouth or in water and has acceptable taste properties for children. It is currently being tested in a pivotal clinical Phase III trial in Kenya and Côte d’Ivoire to generate confirmatory data for registration. The new drug is being developed by the Pediatric Praziquantel Consortium, a public-private partnership led by Merck KGaA, Darmstadt, Germany, which addresses the medical needs of preschool-aged children infected with schistosomiasis.

“A world free of schistosomiasis is possible. With the new medication, we will be one important step closer to reaching this goal,” said Jutta Reinhard-Rupp, Head of the Global Health Institute at Merck KGaA, Darmstadt, Germany, and Chair of the Pediatric Praziquantel Consortium.

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Within the scope of its Schistosomiasis Elimination Program, Merck KGaA, Darmstadt, Germany, has been fighting this NTD with its partner, the World Health Organization, since 2007. The company has donated more than 1.3 billion tablets of praziquantel, enabling treatment of 520 million school-aged children to date. The new medication will be an important building block in this program. Merck KGaA, Darmstadt, Germany, is also involved in several collaborative initiatives that build capacity and strengthen healthcare systems in low- and middle-income countries. These projects invest in local research & development, production and supply chain as well as in health infrastructure, education for behavioral change and training. The set-up of local African production for equitable access to the pediatric medication for schistosomiasis is one example of the collaborative efforts of Merck KGaA, Darmstadt, Germany, to enhance local health capacities in a sustainable manner in order to benefit global health. In this way, Merck KGaA, Darmstadt, Germany, addresses the key requirements of the World Health Organization's 2030 Roadmap for NTDs and also contributes to the United Nations' Sustainable Development Goals (mainly SDGs 3, 8, 9, and 17), in line with the company's [sustainability strategy](#).

About schistosomiasis

Schistosomiasis is a chronic condition and one of the most common and most devastating parasitic diseases in tropical countries. It is estimated that more than 240 million people are infected worldwide and that around 200,000 die from it each year. Flatworms transmit the disease. It is widespread in tropical and subtropical regions where large sections of the populations have no access to clean water and sanitary installations. People become infected with the parasite via 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 school-aged children.

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 1.3 billion tablets have been donated, enabling the treatment of 520 million school-aged children. 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, is donating up to 250 million tablets to WHO. The planned annual donation has a value of USD 32.5 million. 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), health education, 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 Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across healthcare, life science and electronics. Around 58,000 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 advancing

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gene editing technologies and discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices – the company is everywhere. In 2020, Merck KGaA, Darmstadt, Germany, generated sales of € 17.5 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 EMD Serono in healthcare, MilliporeSigma in life science, and EMD 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.

About Universal Corporation Limited

Established in the year 2000, Universal Corporation Limited (UCL) is one of Kenya’s leading pharmaceutical companies with a consumer facing business model in Sub-Saharan Africa. The company has an “in Africa for Africa” strategy with a product range of 100+ products supplied in over ~20 countries. UCL’s manufacturing facility is one of the very few WHO prequalified facilities in Sub-Saharan African region. UCL is a subsidiary of Strides Pharma Science Limited, India. Additional information is available at the Company’s website at www.ucl.co.ke