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Merck KGaA, Darmstadt, Germany and Baylor College of Medicine Announce Collaboration to Advance a Vaccine Manufacturing Platform to Fight Covid-19

- **Company will focus on process development and improvements for manufacturing Baylor's Covid-19 vaccine candidates**

Darmstadt, Germany, May 27, 2020 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, and Baylor College of Medicine today announced today announced an extension of an on ongoing collaboration between Baylor and the Life Science business of Merck KGaA, Darmstadt, Germany to advance a manufacturing platform to fight Covid-19, designed to accelerate transition to Phase 1 clinical trials.

"Vaccine manufacturing is extremely complicated, so we are collaborating on a process development approach to accelerate manufacturing of Baylor's Covid-19 vaccine candidates," said Udit Batra, member of the Executive Board and CEO, Life Science business of Merck KGaA, Darmstadt, Germany. "To fight this pandemic, we will need to produce an unprecedented amount of vaccine in a very short period of time, and we need as many approaches as possible to be successful."

There are no standard manufacturing templates or processes due to the complexity and diversity of vaccine modalities, which makes production a challenge for every organization racing to develop a safe and effective Covid-19 vaccine. Using key learnings from their ongoing collaboration on a schistosomiasis vaccine, the Life Science business of Merck KGaA, Darmstadt, Germany, along with researchers at Baylor College of Medicine and the Texas Children's Hospital Center for Vaccine Development, is optimizing the production process to advance two Covid-19

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vaccines, including the CoV RBD219-N1 vaccine expected to enter clinical trials later this year. The Life Science business will help to accelerate their suitability for large-scale manufacturing. This collaboration will focus on improvements to production efficiency, yield, robustness, scalability and costs.

"Our initial collaboration with the Life Science business of Merck KGaA, Darmstadt, Germany built an important and critical framework for us to quickly validate and ready the production of our portfolio of neglected tropical disease vaccines for global access," said Dr. Peter Hotez, dean of the National School of Tropical Medicine at Baylor College of Medicine and co-director of the Texas Children's Hospital Center for Vaccine Development, alongside Dr. Maria Elena Bottazzi.

"The expansion of our collaboration to include diseases of pandemic importance will now allow us to accelerate the development of a scalable and affordable manufacturing process of our Covid-19 vaccine candidates and enable them to advance as quickly as possible to support vaccine production in low- and middle-income countries," said Bottazzi, who leads the product development activities and serves as associate dean of the National School of Tropical Medicine at Baylor.

The teams will improve the manufacturing platform for the CoV RBD219-N1 vaccine candidate, which was originally developed to target SARS in 2011-2016. Additionally, they will develop a new manufacturing platform for a second Covd-19 vaccine candidate to shorten the time to enter into Phase I clinical trials. The goal for the partnership is to develop a manufacturing process and steps that would lead to a scale-up approach suitable for pilot and later industrial production.

Researchers from the Texas Children's Center for Vaccine Development first formed a partnership with process development scientists and biomanufacturing engineers from the Life Science business of Merck KGaA, Darmstadt, Germany in 2018 to advance vaccine development and production and enhance the response to outbreaks, such as Covid-19. Because the initial groundwork is laid through their existing process development work, the team can quickly shorten the time to the clinic, realizing a key goal.

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Baylor College of Medicine and the Texas Children's Hospital Center for Vaccine Development received funding from NAID for their earlier work in developing the CoV RBD219-N1 vaccine candidate and recently to initiate development of the second Covid-19 vaccine candidate. In addition, Baylor and Texas Children's, through their alliance with PATH, expect to advance the Covid-19 candidates to support access to low- and middle-income countries.

About Merck KGaA, Darmstadt, Germany
Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across healthcare, life science and performance materials. Around 57,000 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 gene editing technologies and discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices – the company is everywhere. In 2019, Merck KGaA, Darmstadt, Germany, generated sales of €16.2 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 EMD Serono in healthcare, MilliporeSigma in life science, and EMD Performance Materials. Since its founding 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.