Saisei Pharma plans clinical study of oral MAF in COVID-19 patients

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Saisei Pharma today announced plans to initiate an international clinical trial. The decision is based on published preclinical evidence, preliminary reports from independent studies and is supported by data of the safety and efficacy of oral MAF in conditions that require the involvement of macrophages as the front line defense in innate immunity. Prior studies have indicated that oral MAF can activate macrophage activity at least three-fold within a few minutes after application. This outstanding phenomenon could play an important role in deploying rapid innate immune response against SARS-CoV-2. The MAF induced phagocytosis enhances antigen processing and their presentation to effector lymphocytes, which is critical in forming the adequate adaptive immune response and synthesis specific antiviral antibodies [1-4]. Enhanced phagocytosis of SARS-CoV-2 viral particles and quicker effective innate and adaptive immune responses increase the probability of the abortive or shorter infection course. In addition to reduced viral load, MAF can downplay hyperactive proinflammatory response causing respiratory failure.

"The efficient innate immune response against SARS-CoV-2 is critical since there is no pre-existing immunity to exotic coronaviruses in humans who were not exposed to it earlier. The potent effect of Saisei Pharma MAF on phagocytosis is not accompanied by clinical or biochemical signs of inflammation when administered to humans. This means that our innate immunity can fight off pathogens without causing inflammation and associated respiratory deterioration" said immunologist Dr. Galyna Kutsyna, MD/PhD.

"Saisei Pharma is taking a number of steps to address the urgent need arising from the COVID-19 pandemic," said Dr. Toshio Inui, MD, Head Global Drug Development and Chief Medical Officer. *"The potential that oral MAF could lead to faster recovery for COVID-19 patients with fewer requiring intensive care and mechanical ventilation is encouraging and merits further investigation. While oral MAF is very safe, its safety and efficacy profile has not yet been established with regards to COVID-19."*

Given the global spread of the pandemic, and as plans for the study are being finalized, Saisei Pharma also has set up an international compassionate use program for eligible patients, subject to local approvals. In addition, steps are taken to manage the anticipated increase in COVID-19 related requests for oral MAF without interrupting access for patients taking oral MAF for its current indications. Saisei Pharma intends to join key industry partners against COVID-19 to complement the array of available therapy options. To support access, Saisei Pharma is committed to keeping stable prices for its range of products that may help in the treatment of COVID-19.

About Saisei Pharma oral MAF

Clinically active form of oral MAF is derived from enzyme-treated dairy products. MAF resulted from decades-long R&D activity by Saisei Pharma aimed at improving production technology and ensure the product's higher activity and stability. The final goal is to make oral MAF available globally for conditions involving inadequate immune response due to macrophage dysfunction and hyper immune-inflammatory disorders in adult and pediatric patients. Saisei Pharma has filed a series of patents in Japan, EU, USA, and worldwide which relate to the technology, comprising the composition and method of production. Oral MAF is available as a health food or immunomodulating supplement in several countries, e.g., USA, Spain, Lithuania, and Ukraine. The exact indication for oral MAF varies by country. Additional worldwide regulatory filings are underway in other countries. Information about Saisei Pharma is available on the company website http://www.saisei-pharma.co.jp.

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Disclaimer

This press release contains forward-looking statements regarding potential marketing approvals, new indications or labeling for oral MAF, regarding potential future revenues from such products, regarding our plans to initiate a clinical trial to evaluate the use of oral MAF in COVID-19 patients, or regarding the international compassionate use program for eligible patients. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize,

or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There is no guarantee that oral MAF will be submitted or approved for sale or for any additional indications or labeling in any market, or at any predetermined time. Neither can there be any guarantee that we will initiate the planned clinical trial in the expected time frame. Nor can there be any guarantee that oral MAF will meet the primary or secondary endpoints of the planned trial. Neither can there be any guarantee that oral MAF will be commercially successful in the future. Our expectations regarding Saisei products and the international compassionate use program could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; prescribing preferences of physicians and patients; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors. Saisei Pharma is providing the information in this press release as of this date and does not undertake any obligation to update forward-looking statements contained in this press release as a result of new information, future events or otherwise.