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Huma receives multi-condition US FDA 510(k) Class II regulatory clearance for its configurable SaMD disease management platform

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a a NEW YORK and LONDON, June 12, 2023 /PRNewswire/ -- Huma Therapeutics ("Huma"), a leading global digital health company, today announced that it has received U.S. Food and Drug Administration (FDA) Class II clearance for its disease-agnostic Software as a Medical Device (SaMD) platform. This clearance marks a significant milestone in patient monitoring and disease management. Huma's SaMD platform powers digital health pathways through which data are collected from patients for self-management or to be assessed remotely by healthcare professionals. Huma's technologies include remote patient monitoring systems and companion apps to enable disease management. Achieving Class II clearance means the platform is permitted to monitor patients of all ages with any condition - including paediatrics, and in pregnancy. The platform is also device-agnostic and can integrate with external third-party devices such as heart rate and blood sugar monitors, as well as smart inhalers, enhancing its capabilities and versatility. AI algorithm additionClass II level clearance permits Huma's platform to host artificial intelligence algorithms that use automated data analytics to support screening, diagnosis, dosing recommendations, clinical decision making and prognostication. By harnessing this new functionality, healthcare providers can identify at risk patients, intervene early and deliver high quality care more effectively. Class II clearance further enables greater support for patients to drive self-management who display early signs and symptoms that may indicate disease progression and more serious and avoidable events. As part of the platform approval, Huma's cardiovascular risk score algorithm, currently being rolled out as part of a nationwide screening programme in the US aimed at improving cardiovascular health, was also FDA 510-K cleared. Dan Vahdat, CEO & Founder of Huma, said: "We are delighted to see our software as a medical device platform cleared for Class II use by the US FDA so that we can provide next-generation health insights and predictions. This clearance adds to the platform's recent EU MDR Class IIb approval, making it one of the best regulated such technologies globally. Now, our partners can launch Class II regulated software for new diseases and use cases in a matter of weeks on our platform, rather than the years they may have taken to develop and regulate their own solution. We are really excited to see how regulated SaMD, validated algorithms and GenerativeAI can enable our partners to care for more patients with less." Watch Dan explain the importance of FDA Class II clearance to Huma and to the field of digital health. Dr Rishi Patel, Cardiology Service Line Medical Director, Banner Medical Group, Arizona, said: "I am delighted to see Huma achieve Class II clearance from the US FDA for its technology platform. As a potential partner, this level of clearance gives us confidence that we are working with a highly regulated, safe and

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evidence-based platform in our care and management of patients." Dr Mert Aral, Chief Medical Officer at Huma, said: "Our SaMD platform is used in the diagnosis, treatment, and monitoring of a wide range of diseases, and it is therefore important that it meets the high regulatory standards to demonstrate its safety and effectiveness based on evidence. There is significant inconsistency in the quality of care patients receive today and fragmentation in implementation of guideline directed disease management. The ability of the Huma platform to provide advanced clinical decision support and host algorithms that can diagnose and quantify disease processes will be a game changer for tackling this issue at scale." Huma is one of the first applicants to be successful through the FDA's new, interactive joint eSTAR programme (with Health Canada) for a comprehensive medical device submission. Huma's compliance with IEC 60601-1-8 now allows the platform to conduct data interpretation triggering on-time alerts, enhancing personalised, clinical decision support and patient notifications. About HumaHuma Therapeutics is a global digital health technology company that advances digital-first care delivery and research to help people live longer, fuller lives. Huma's award-winning modular platforms are used by more than 3,000 hospitals and clinics, with 1.8+ million active users in healthcare and 650,000+ participants across research. Huma's regulated Software as a Medical Device is the only disease agnostic platform to hold both EU MDR Class IIb and US FDA Class II regulatory status. It powers: Please visit www.huma.com and follow us on LinkedIn at Huma Media contactKaren Birmingham PhDHead of PR & Communications, +44 (0) 7866 609314 Logo - https://mma.prnewswire.com/media/1427908/Huma_Logo.jpg