Astellas and Welldoc Pair Up FOR DIGITAL THERAPEUTICS

▶ *Trend Watch: Pharma's Use of Healthtech Continues to Gain Ground*

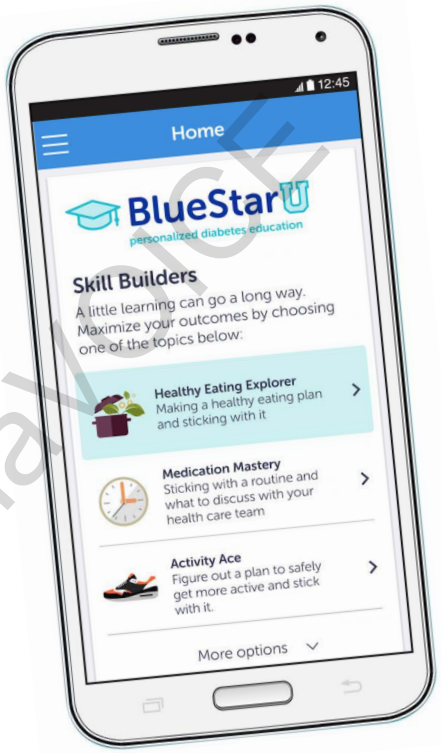
Astellas Pharma and Welldoc have entered into a collaboration and license agreement directed toward the development and commercialization of digital health solutions. Under the agreement, Astellas and Welldoc will jointly develop and commercialize a digital health solution called BlueStar in Japan and other Asian markets for patients with diabetes; collaborate to broaden the adoption of BlueStar in the U.S. market; and jointly develop and commercialize digital therapeutics in other areas globally.

The FDA approved BlueStar for use by healthcare providers and their patients 18 years of age and older who have type 1 or type 2 diabetes. BlueStar not only assists patients in managing their disease by capturing, storing, and transmitting blood glucose data and tracking medication, diet, activity, and exercise, it also uses individual patient treatment data and machine learning to provide tailored motivational, behavioral, and educational coaching messages to aid in diabetes self-management.

Under the terms of the agreement, Astellas will make an up-front payment of $15 million to Welldoc. In addition, the agreement includes development and commercialization milestones as well as royalties on any future product sales.

"Welldoc is excited to collaborate with Astellas as part of our evolution as a digital health company with a commitment to help improve the health of those living with chronic disease," says Kevin McRaith, president and CEO of Welldoc. "Astellas is a critical partner as Welldoc looks to broaden our platform into other disease areas as well as expand into other global markets."

In addition to assisting patients in managing their disease in line with the guidelines compiled by the American Association of Diabetes Educators, namely, taking medication, eating well, and being active, it offers a management method for individual patients' blood glucose levels made possible by machine learning and artificial intelligence that uses compiled treatment data to provide tailored coaching messages to aid in diabetes self-management. BlueStar also comes with a diagnosis support system for physicians, which allows patients to share data on blood glucose levels, medication, and physical conditions, as well as the status of progress, with physicians before examination.



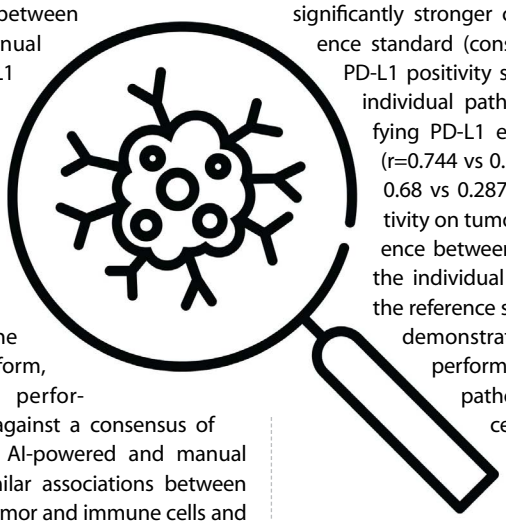
Janssen Leverages Wearable Technology to REIMAGINE CLINICAL TRIAL DESIGN

The Janssen Pharmaceutical Companies of Johnson & Johnson have launched the first-ever completely decentralized, mobile, indication-seeking clinical study, called CHIEF-HF. To accelerate the study and fast-track results, all contact with participants will be done virtually, with no in-person clinical visits required. Drawing on previous experience, Janssen is using smart technology and wearable devices to more quickly and efficiently gather and analyze real-world evidence to assess the effectiveness of canagliflozin in adults with heart failure (HF), with or without type 2 diabetes (T2D). Through a collaboration with research organization PRA Health Sciences and its innovative mobile clinical trial platform, CHIEF-HF (Canagliflozin: Impact on Health Status, Quality of Life and Functional Status in Heart Failure), will examine the use of canagliflozin compared to placebo on quality of life improvement scales, in participants with either preserved or reduced ejection fraction HF.

"Through the CHIEF-HF study, we are exploring how we can harness technology that consumers already have at their fingertips, including smartphones and wearable devices, to change this paradigm," says Paul Stoffels, M.D., vice chairman of the executive committee and chief scientific officer, Johnson & Johnson. "Through this virtual trial approach, we hope to make studies more inclusive, faster, and more cost-effective, to deliver innovative solutions to the people who need them."

AI-based Approaches Accurately Quantified PD-L1 Expression ON TUMOR AND IMMUNE CELLS

PathAI and Bristol-Myers Squibb presented results of a robust, retrospective analysis examining PD-L1 expression on tumor and immune cells from 1,079 patient samples across three randomized Phase III clinical trials evaluating Opdivo (nivolumab) in non-small cell lung cancer. The study found a strong correlation between AI-powered and manual quantification of PD-L1 across tumor cells, macrophages, lymphocytes, and total immune cells.



In the study, after training a model with more than 250,000 pathologist-provided annotations using the PathAI research platform, algorithm analytic performance was assessed against a consensus of five pathologists. The AI-powered and manual approaches found similar associations between PD-L1 expression on tumor and immune cells and progression-free survival.

In a related analysis, PathAI and Bristol-Myers Squibb researchers retrospectively examined samples from 293 patients across two clinical trials of Opdivo in advanced urothelial cancer. The AI-powered PD-L1 assessment showed a significantly stronger correlation with the reference standard (consensus of five pathologist PD-L1 positivity scores) compared with the individual pathologist scores for quantifying PD-L1 expression in lymphocytes (r=0.744 vs 0.598) and macrophages (r= 0.68 vs 0.287). In assessing PD-L1 positivity on tumor cells, there was no difference between the PathAI platform and the individual pathologist scores versus the reference standard (r=0.837 vs 0.857), demonstrating the PathAI platform performed similar to or better than pathologist-based scoring in all cell types tested, and especially for immune cells where manual correlation is known to be low.

Abbott, Omada Add mHealth Coaching TO DIABETES CARE MANAGEMENT

Abbott and Omada Health are partnering on an mHealth platform for businesses and health plans. Abbott Laboratories will integrate its FreeStyle Libre continuous glucose monitoring system with a connected health coaching platform developed by Omada Health, giving people living with type 2 diabetes access to care management alongside their blood glucose readings.

The deal is the latest in an ongoing effort in mHealth and telehealth circles to create an integrated platform that combines blood glucose sensing, personalized coaching and insulin delivery. To that end, Abbott is currently working with companies like Novo Nordisk, Sanofi, and Tandem Diabetes Care to integrate the FreeStyle Libre platform with insulin pens and other delivery systems.

The Abbott-Omada partnership is designed to add self-management and remote monitoring to the mix, giving consumers instant access to resources and coaching when it's most needed.

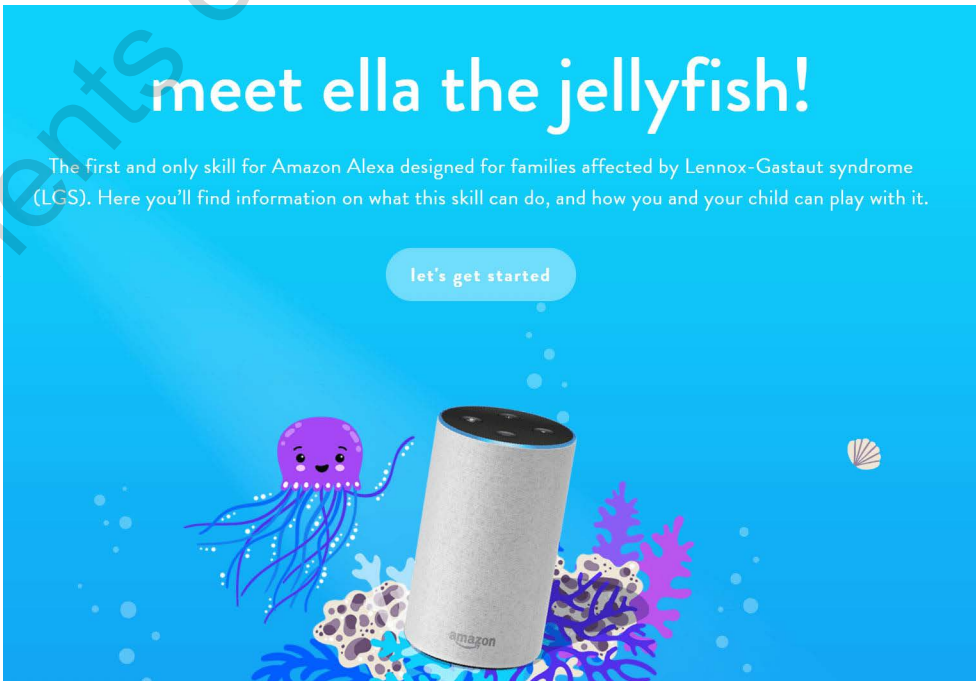
Eisai's Ella the Jellyfish Engages with CHILDREN LIVING WITH LGS EPILEPSY

Eisai has designed Ella the Jellyfish, the first Amazon Alexa skill for those affected by Lennox-Gastaut Syndrome (LGS). The Alexa skill was created with input from children living with LGS, a rare and severe form of childhood-onset epilepsy, their families, and caregivers and is provided free of charge.

Featuring capabilities such as interactive play, listening, and creative activities, Ella the Jellyfish was designed for easy and seamless daily use on Alexa-enabled devices, including voice assistants, mobile phones, and tablets. Caregivers and children can instantly and easily interact with Ella and her underwater friends by listening to Ella tell a story, singing a song, listening to a relaxing meditation, or playing games.

Parents and guardians can enable the Ella the Jellyfish skill by searching for Ella the Jellyfish in the Alexa Skills Store online and through the Alexa app.

Having a child who has LGS can significantly change the family routine and sibling relationships, especially as they get older. The frequent, unpredictable seizures, often associated with falls or injuries, require the child with LGS to have constant supervision. This results in 24-hour-a-day, seven-day-a-week care, often putting a tremendous strain on the marriage and family.



"Ella the Jellyfish was born out of the countless, heartfelt experiences Eisai employees have had with the LGS community," says Alexander Scott, chief strategy officer, neurology business group, Eisai Inc. "Staying true to our human healthcare mission to advance epilepsy care and help address the specific needs of patients and their families is what inspired us to develop Ella. Our goal is to relentlessly break through ordinary approaches so that we may provide innovative solutions that go beyond just the medicine."