Syapse, FDA, and Advocate Aurora Health to Present Pneumonitis Safety Data in Plenary Talk at AACR Virtual Meeting

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Data presented demonstrates that patients with a past medical history of pneumonitis had a higher incidence of treatment associated pneumonitis in both clinical trial and real-world data

AACR Virtual Annual Meeting Plenary Session April 27, 2020 at 4:00 PM EDT

SAN FRANCISCO, April 27, 2020 (GLOBE NEWSWIRE) -- Syapse announced that research results stemming from its Research Collaboration Agreement with the U.S. Food and Drug Administration (FDA) will be presented today at the Clinical Plenary Session of the American Association for Cancer Research (AACR) Virtual Annual Meeting. The session will discuss a joint abstract, titled "*Pneumonitis incidence in patients with non-small cell lung cancer treated with immunotherapy or chemotherapy in clinical trials and real-world data*," that highlights work conducted as a collaboration between Syapse, the Office of Clinical Pharmacology (OCP) within the FDA Center for Drug Evaluation and Research (CDER), and Advocate Aurora Health. Results of this research will be presented by Dr. Qi Liu, PhD, MStat, FCP, Senior Science Advisor, Office of Clinical Pharmacology, Office of Translational Sciences at the US FDA CDER, and will be the subject of a discussion session immediately following.

Immunotherapies have seen rapid adoption since approval and are widely used in lung cancer treatment, but the long-term safety profiles of these drugs compared with traditional chemotherapies are not yet well characterized. Pneumonitis, or inflammation of the lungs, is a known potential side effect of cancer treatments, particularly for patients receiving immunotherapies. Understanding how a patient's medical history influences the likelihood of pneumonitis and other safety outcomes in a real-world setting is critical for clinicians to appropriately weigh the risk-benefit profile of a drug for a given patient.

In this study, Syapse, the FDA OCP, and Advocate Aurora Health examined the frequency of treatment-associated pneumonitis in patients with advanced non-small cell lung cancer (NSCLC) who were treated with immunotherapy or chemotherapy. The design for this study enabled a direct comparison of safety outcomes in the clinical trial setting with those in a real-world setting, as well as the development of novel clinical insights.

Patients with a prior history of non-infectious pneumonitis experienced a higher incidence of treatment associated pneumonitis when receiving both classes of therapy, but incidence was higher for patients receiving immunotherapy than for chemotherapy. Trends were similar across both clinical trial data and real-world data. The complete abstract and data table detailing our results can be found on the AACR website. A discussion of the implications of these results and other aspects of the study by Thomas Brown, MD, MBA, Chief Medical Officer at Syapse and senior author of the study, can be found on the Syapse blog.

Understanding the real-world incidence of these types of safety events has historically been difficult to achieve due to the disparate systems in which relevant data is stored and the fragmentation of care across distinct, unconnected providers. A core goal of the Syapse-FDA Research Collaboration Agreement has been to characterize the value of a multi-source approach to developing real-world

evidence that combines clinical data from medical oncology outpatient clinics, hospital EHRs, non-oncology clinics, registries, and other sources across integrated health systems with molecular data from testing labs. By applying this approach in partnership with an integrated health system such as Advocate Aurora Health, whose records span across the continuum of care, the collaboration was able to conduct safety research that has historically been difficult to perform outside of a clinical trial setting.

This study provides a blueprint for conducting rigorous research on safety outcomes using real-world evidence in the future. In particular, the methodology can easily be extended to focus on patients with a prior history of infectious pneumonitis, i.e. pneumonia. Given that the COVID-19 pandemic will likely significantly increase the percentage of the population with a prior history of pneumonia, studies designed to understand the safety outcomes of these patients will be critical to informing future clinical practice.

“We are proud of this work and the collaborations we have built with both the FDA and Advocate Aurora Health, a member of the Syapse Learning Health Network. The honor of being selected for a plenary session presentation at AACR underscores the value and novelty of conducting this type of safety research using real-world data,” said Thomas Brown, MD, MBA, Chief Medical Officer at Syapse. “This is clinically meaningful research with potentially practice-changing implications in precision oncology patient care.”

“Clinicians and regulators are interested in real-world safety profiles to develop new practices for managing risk and evaluating potentially beneficial therapies when comorbidities such as pneumonitis are present,” said Michael A. Thompson, MD, PhD, FASCO, medical director of the Early Phase Cancer Research Program and co-director of the Oncology Precision Medicine Program at Advocate Aurora Health. “This research provides encouraging new data that clinicians can use to better understand the post-approval behavior of drugs in the real world. This is especially important for safety issues because they often manifest over long periods of drug exposure on an individual or population basis.”

The plenary presentation covering this work will take place at AACR Virtual Meeting 1, on Monday, April 27 at 4pm EDT during the Lung Cancer Targeted Therapy Session within the Clinical Plenary Session. Free registration to the virtual meeting can be found at: https://cloud.aacr-outbound.com/virtual-am20.

About Syapse
Syapse is on a mission to deliver the best care for every cancer patient through precision medicine. Our insights platform, data sharing network, and industry partnerships enable healthcare providers to bring precision cancer care to every patient who needs it. By bringing together leading healthcare innovators into a unified ecosystem, we have built one of the world’s largest learning health networks of provider-driven precision medicine data. In collaboration with our health system partners, we are working toward a future in which all cancer patients have access to the best personalized care, regardless of location or income.

About the Syapse-FDA Research Collaboration Agreement
In August 2019, Syapse and the U.S. Food and Drug Administration (FDA) Oncology Center of Excellence (OCE) signed a multi-year Research Collaboration Agreement focused on the use of real-world evidence to support regulatory decision-making. Syapse and the OCE are working with stakeholders across the FDA to address key regulatory questions about testing and treatment patterns, dosing and safety, and outcomes in oncology, with a focus on precision medicine.

About Advocate Aurora Health
Advocate Aurora Health is one of the 10 largest not-for-profit, integrated health systems in the United States and a leading employer in the Midwest with more than 70,000 employees, including more than 22,000 nurses and the region's largest employed medical staff and home health organization. A national leader in clinical innovation, health outcomes, consumer experience and value-based care, the system serves nearly 3 million patients annually in Illinois and Wisconsin across more than 500 sites of care. Advocate Aurora is engaged in hundreds of clinical trials and research studies and is nationally recognized for its expertise in cardiology, neurosciences, oncology and pediatrics. The organization contributed $2.1 billion in charitable care and services to its communities in 2018. We help people live well.

Plenary Presentation Information
Session: Lung Cancer Targeted Therapy
Abstract ID: CT086
Title: Pneumonitis incidence in patients with non-small cell lung cancer treated with immunotherapy or chemotherapy in clinical trials and real-world data
Presenter: Dr. Qi Liu, PhD, MStat, FCP, Senior Science Advisor, Office of Clinical Pharmacology, Office of Translational Sciences at US FDA CDER
Date/Time: Monday, April 27, 2020, 4:00pm - 4:10pm ET

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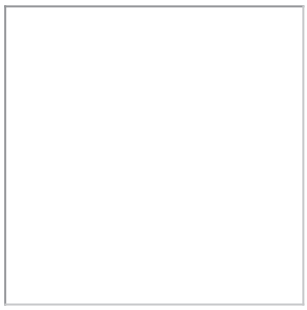

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