U.S. Physicians Overwhelmingly Support Current FDA Data Standards, Switching Studies for Interchangeable Biosimilars; Oppose Pharmacy Substitution of Non-Interchangeable Biosimilars

FOR IMMEDIATE RELEASE

September 4, 2024

Arlington, VA- U.S. physicians overwhelmingly support maintaining the Food and Drug Administration's (FDA's) current data standards for interchangeable biosimilars and oppose treating all biosimilars as interchangeable with the originator biologic medicines they copy, according to a recent survey of 270 U.S. physicians. The August 2024 survey, conducted on behalf of the Alliance for Safe Biologic Medicines, documents the perspectives of specialists from nine practice areas in which biologic medicines are routinely prescribed, including gastroenterology, oncology, rheumatology, and others.

"All FDA-approved biosimilars are safe and effective, but treatment plans are not universal or "one-size-fits-all", explains ASBM Chairman Ralph McKibbin, MD. "Each is uniquely tailored, and patients frequently try several products before finding one that best stabilizes their condition. Physicians need to be confident that a substitution by a pharmacy or insurance company won't disrupt a patient's hard-won treatment stability. The interchangeable standard's rigorous data requirements, often including switching studies, provide that assurance."

Key Findings from the Survey:

- **88% of physicians agree that switching studies increase their confidence** in the safety of switching patients from an originator medicine to an interchangeable biosimilar
- **87%** of physicians prefer switching patients to a biosimilar **only if it has been rigorously evaluated for its impact on safety and efficacy when switched from an originator biologic**.
- **88%** believe an interchangeable biosimilar should undergo individual evaluations to determine the impacts of switching on patient safety and efficacy.
- **Only 11% of respondents are in favor of deeming all biosimilars as interchangeable without these evaluations.**
- **85%** agree that biosimilars should only be considered interchangeable if they have been specifically assessed for safety and efficacy in switching scenarios.

In the U.S. as in most advanced nations, a prescribing physician may substitute any biosimilar for its reference product. But because biosimilars are not identical to their reference products, pharmacy substitution is controversial, opposed by majorities of physicians worldwide, and banned in many countries including most of Western Europe. Under U.S. state laws, only biosimilars deemed "interchangeable" by the FDA may be substituted at the pharmacy without physician involvement the way generic drugs are. "These laws were passed with the support of state medical societies nationwide, which was conditional on pharmacy substitution being limited only to interchangeable biosimilars", notes ASBM Executive Director Michael Reilly.

The survey's results are consistent with prior surveys, says Reilly: "A 2021 survey revealed that while 89% of U.S. physicians are confident in the safety and efficacy of biosimilars; 69% believe only the physician and patient should determine which biologic to use, not a third-party such as a pharmacy or insurance company. But the majority (59%) are more comfortable with a pharmacy-level substitution of an interchangeable because of the additional safety and efficacy data currently required. The FDA's standards are working. Any effort to lower them could compromise the progress we've made in building physician and patient confidence in biosimilars."

ASBM shared the survey findings with the FDA as part of a public comment period on draft guidance that proposes to lower the data requirements for demonstrating interchangeability. The U.S. Senate is also considering a bill that would deem all biosimilars interchangeable and severely restrict the FDA's ability to ask for additional data.

###

About the Alliance for Safe Biologic Medicines

The Alliance for Safe Biologic Medicines (ASBM) is an organization of patients, healthcare providers, and manufacturers committed to ensuring that biosimilar medicines are introduced in the U.S. in a patient-centered way with transparent policies based on sound science and effective regulation. Learn more at www.SafeBiologics.org