Important Information for Patients About SD-101 for Epidermolysis Bullosa

We recently learned that Ei, our manufacturer of drug product for SD-101, received an FDA warning letter in April 2018 for the inspection they had in October of last year, **unrelated to our product**. The warning letter referenced GMP deficiencies with respect to Ei's manufacturing processes. The FDA warning letter was recently posted to the FDA website through the following link: https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm606805.htm

Although SD-101 is not mentioned in the FDA warning letter, it was produced during the same time frame and using the same equipment as noted in the warning letter. As a result, we are exercising caution to ensure patient safety. In order to avoid any potential risk, Amicus has decided to withdraw all SD-101 product that is currently used or planned for use in the extension studies and expanded access program. As previously announced, the SD-101 program for epidermolysis bullosa (EB) was discontinued and there are no outstanding orders for any additional production of SD-101 at this facility.

Since our announcement of the top-line data, we have been in the process of closing out the ongoing, open-label extension studies of SD-101 (SD-004 and SD-006). Given the recent warning letter, we are accelerating our efforts to close out these studies as well as our expanded access program for SD-101.

While we feel we must withdraw the remaining product, we are very disappointed. As a global, patient-centric biotechnology company it is our commitment at Amicus to deliver only the highest quality medicines for people living with rare diseases. It is our goal to continue to support the EB community and help better understand this devastating disease.

All patients still receiving SD-101 via ongoing studies (ie. studies SD-004 or SD-006) or expanded access will be contacted by participating sites and instructed to stop using SD-101 immediately and schedule an End of Study Visit. Patients/caregivers should bring all used and unused SD-101 tubes to the End of Study visit. End of Study visits should occur on or before September 14, 2018.

More information for patients is also available for patients through our toll-free Global Patient & Professional Advocacy number (866-926-4287) for the U.S. and Canada in addition to (+44-1753-888-567) for Patient Advocacy International. Or e-mail inquiries to patientadvocacy@amicusrx.com or patientadvocacyintl@amicusrx.com