AspenBio Pharma Submits Pre-IDE Information Package to FDA for AppyScore Appendicitis Test System

CASTLE ROCK, Colo./PRNewswire/ -- AspenBio Pharma, Inc., an in vitro diagnostic company, announced that it has submitted a pre-IDE (Investigational Device Exemption) information package to the U. S. Food and Drug Administration (FDA) for the use of the AppyScore™ test system to aid physicians in evaluating children and young adult patients at low risk for acute appendicitis, allowing for more conservative patient management. In conjunction with the pre-IDE package, AspenBio has scheduled a meeting with the FDA prior to the end of the third quarter to work cooperatively on the clinical and regulatory plan.

Steve Lundy, President and CEO of AspenBio, commented, "The pre-IDE submission with the FDA is a significant milestone on our path to advance AppyScore towards commercialization. Following feedback from our upcoming meeting with the FDA, we plan to initiate the pivotal clinical trial for AppyScore."

The pre-IDE documentation has been submitted to the FDA in order to obtain the agency's guidance regarding the regulatory pathway; the proper approach to refine the clinical and statistical plan; and to ensure AspenBio is working closely and cooperatively with the FDA review team. The basis for pre-IDE submission is data from an analysis of more than 500 patient samples collected in AspenBio's 2011 pilot trial.

Pre-IDE submissions and meetings are strictly voluntary, and any comments or recommendations made in the review of protocols or during these meetings are not binding on the FDA or the Company.

About AspenBio Pharma
AspenBio Pharma, Inc. is an in vitro diagnostic company focused on the clinical development and commercialization of its lead product, AppyScore. AppyScore is a unique blood-based test with projected high sensitivity and negative predictive value that is designed to aid in the identification of patients at low risk for acute appendicitis, allowing for more conservative patient management. AppyScore is initially being developed for pediatric, adolescent and young adult patients with abdominal pain as this population is at the highest risk for appendicitis as well having the highest risk of the long-term health effects associated with CT imaging. For more information, visit www.aspenbiopharma.com [1].

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