

FOR IMMEDIATE RELEASE

Contact: Laura Gordon
Phone: 301-605-7571
Email: laura.gordon@iactc.org

**Chiesi Joins the Institute for Advanced Clinical Trials for Children
as Newest Annual Member**

Rockville, MD, April 24th, 2019 – The Institute for Advanced Clinical Trials for Children today welcomes Chiesi Farmaceutici as its newest Annual Member. I-ACT is a non-profit organization focused on improving the quality, speed and efficiency of global pediatric studies to address the gap in evidence on the best use of therapeutics in children.

“The need to improve pediatric clinical trials is urgent, as these trials are the critical step in generating the data required to allow safe and effective use of new medicines and devices in pediatric populations,” said Laura Gordon, CEO of I-ACT for Children. “Chiesi’s membership in I-ACT for Children demonstrates its commitment to this goal.”

“We are delighted to start this promising collaboration with I-ACT, given their highly relevant experience in the field, which we believe will synergize with Chiesi’s commitment and track record in innovating, developing and registering therapeutic solutions, particularly focused in the area of neonatology with the objective to address significant unmet medical needs in this delicate patient population,” said Paolo Chiesi, Vice President and R&D Director of Chiesi Farmaceutici.

Pediatric clinical trials face a variety of unique hurdles. More than 60 percent of pediatric clinical trials stall and 40 percent fail. As a result, it takes an average of nine years for an adult therapy to secure pediatric labeling. Barriers to efficient, successful pediatric trials include issues with trial designs that haven’t been properly adapted for children, difficulty identifying enough qualified patients and until recently, lack of a dedicated clinical trial infrastructure that can be quickly activated when a therapy or device is ready for testing.

I-ACT for Children was created to identify and find solutions for these and other critical barriers. It has built a network of pediatric trial sites that will share common training tools and best practices and are coordinated under the I-ACT for Children umbrella. Study and site feasibility can be assessed through real world data analysis to determine factors such as which sites have enough patients with a given disease or condition to enroll in a trial. A quality improvement

system will be launched this year within the site network to measure and track each site's ability to speed start-up and enrollment time, retain patients in a trial and reduce time to completion.

I-ACT for Children also works with its members to introduce innovative study designs that produce advances such as reducing sample size and adapting study endpoints to better reflect the pediatric population.

About the I-ACT for Children

I-ACT for Children is a 501(c)3 that serves as a neutral and independent organization on behalf of children everywhere, bringing a dedicated voice to the advancement of new medicines and devices needed now and in the future. Its work is to engage public and private stakeholders through research and education to ensure that healthcare for children is continually improved by enhancing the awareness of, support for and success of pediatric clinical trials.

To learn more about I-ACT, visit www.iactc.org

About Chiesi Farmaceutici

Based in Parma, Italy, Chiesi Farmaceutici is an international research-oriented group with over 80 years' experience in the pharmaceutical sector and is present in 28 countries. The group researches, develops and commercializes innovative medicines in the respiratory disease, special care and rare disease therapeutic areas. The Group's Research & Development center is based in Parma (Italy) and integrated with 6 other important research and development groups in France, the USA, the UK and Sweden, to promote its pre-clinical, clinical and registration programs. The Group employs around 5,700 people. For more information, please visit www.chiesi.com

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