PRESS RELEASE

A new clinical framework redefines the diagnosis of COPD Exacerbations

- The recommendations of an international expert panel to update the definition and severity classification of chronic obstructive pulmonary disease (COPD) exacerbations will be presented by Professor Bartolome R. Celli at the 2021 International Meeting on Asthma and COPD in Florence
- Physicians will be able to use simple clinical tools to more accurately diagnose the acute episode and to classify its severity at point of contact
- In addition, it suggests other acute conditions from which exacerbations need to be differentiated
- The 'Rome Proposal' attempts to establish a platform for more accurate treatment and better quality of life for patients suffering from COPD exacerbations

CARY, N.C., December 20, 2021 – Chiesi USA (key-ay-zee), the U.S. affiliate of Chiesi Farmaceutici, the international research-focused pharmaceuticals and healthcare Group (Chiesi Group), welcomes the findings of an international panel of expert clinicians gathered to re-define the clinical pathways for diagnosing and classifying exacerbations of chronic obstructive pulmonary disease (ECOPD) at the 2021 International Meeting on Asthma and COPD hosted in Florence, Italy.

The "Rome Proposal" structures the diagnosis of ECOPD around a set of well-established, measurable and clinically relevant markers. This will allow clinicians to establish ECOPD occurrences based on objective metrics, thus removing the uncertainties arising from patients' subjective description of their symptoms and unconscious bias. Together with a novel severity scale for ECOPD, the "Rome Proposal" enables a better assessment of the level of acute care that patients require.

Based on a Delphi methodology implemented by an international panel of experts, the "Rome Proposal" offers a new framework for physicians worldwide to diagnose ECOPD more accurately in the case of acutely worsening respiratory symptoms. It establishes a set of six clinically measurable variables, which clearly indicate an acute case of ECOPD: dyspnoea, respiratory and heart rate, SaO_2, hypoxemia and hypercapnia, and serum C-reactive protein levels. While some of these clinical variables have been ascertained as signs of ECOPD in previous clinical guidelines, existing clinical guidelines do not offer clear and measurable thresholds to characterize and grade the pathophysiological event itself[1]. By viewing the symptoms and markers in relation to each other, physicians will also, for the first time, be able to perform a differential diagnosis against other acute conditions (e.g., heart failure, pneumonia, thromboembolism), where similar symptoms may be present, but associated with different signs, imaging and/or biomarkers[2].

Finally, while current clinical definitions and standards only allow ECOPD severity to be classified post-hoc severely impeding the timeliness and quality of patient care, the proposed definition allows diagnosis and assessment of severity at the point of care and thus to properly plan the management accordingly. Based on existing work, whereby ECOPD typically worsens within a maximum of 14 days[3], the "Rome Proposal" establishes an upper time limit to monitor patients' conditions and a clear cut-off point by when care should be administered. This way, the expert panel further removes the ambiguities currently experienced in ECOPD diagnosis.

Supported by Chiesi, the "Rome Proposal" is an important contribution to the global scientific discussion of how to improve care for COPD patients around the world.

Bartolome R. Celli, Professor of Medicine at Harvard Medical School, said: *"Credit must be given to the panel of international experts of multiple specialties who, over one year of intense work, were able to dissect*

[1] Celli et al., Am J Respir Crit Care Med, 2021 Sep 27, doi: 10.1164/rccm.202108-1819PP
[2] Celli et al., Am J Respir Crit Care Med, 2021 Sep 27, doi: 10.1164/rccm.202108-1819PP.
[3] Celli et al., Am J Respir Crit Care Med, 2021 Sep 27, doi: 10.1164/rccm.202108-1819PP.

the literature and, using a methodological approach, provide a final proposal that once validated in prospective studies, should help the field move forward."

Professor Leonardo M. Fabbri, Eminent Scholar of Internal and Respiratory Medicine at the University of Ferrara, added: *"The 'Rome Proposal' highlights the importance of making the right diagnosis and conducting a careful differential diagnosis of the several chronic diseases that are almost invariably associated with COPD in stable conditions, and that may worsen during exacerbations. This includes not only heart failure, pneumonia and thromboembolism but also ischemic heart diseases, arrhythmias, asthma, bronchiectasis, pneumothorax and many others."*

"The 'Rome Proposal' represents an important milestone for better understanding and treating a very important and troubling component of COPD progression and, the prospect for more accurate treatment and better quality of life for people living with this condition," said Gabriele Nicolini, Head of Global Medical Affairs at Chiesi Group. He added that *"the updated definition and severity classification offer physicians a structured methodology and decision-making tool to detect and swiftly respond to ECOPD."*

The full report, including the abstract, framework and methodology, can be found here.

###

About Chiesi USA

Chiesi USA, Inc., headquartered in Cary, North Carolina, is a specialty pharmaceutical company focused on commercialization of products for the hospital and target office-based specialties. The Company is a wholly-owned subsidiary of family-owned Chiesi Farmaceutici S.p.A, a global R&D-focused pharmaceutical company based in Parma, Italy. In the United States, the Company delivers therapies and enhances care for patients in the areas of acute cardiology, neonatology and cystic fibrosis. Recognized as a Certified B Corporation™, Chiesi is dedicated to improving the health and well-being of its communities through its employee-led corporate social responsibility program, Chiesi in the Community. Innovation, collaboration and impact are the cornerstones of the Chiesi culture. For more information, visit www.chiesiusa.com.

About Chiesi Group

Based in Parma, Italy, Chiesi is an international research-focused pharmaceuticals and healthcare group with over 85 years' experience, operating in 30 countries with more than 6,000 employees (Chiesi Group). To achieve its mission of improving people's quality of life by acting responsibly towards society and the environment, the Group researches, develops and markets innovative therapeutic solutions in its three focus areas: AIR (products and services that promote respiration, from new-born to adult populations), RARE (treatment for patients with rare and ultra-rare diseases) and CARE (products and services that support specialty care and consumer-facing self-care). The Group's Research and Development center is based in Parma and works alongside 6 other important research and development hubs in France, the U.S., Canada, China, the UK and Sweden to pursue its pre-clinical, clinical and regulatory programs. Chiesi, since 2019, is the world's largest B Corp certified pharmaceutical group. The global B Corp movement promotes business as a force for good. Moreover, Chiesi Farmaceutici S.p.A. has changed in 2018 its legal status to a Benefit Corporation, by incorporating a double purpose for the creation of shared value, and to generate value for its business, for society and the environment. As a Benefit Corporation, Chiesi Farmaceutici S.p.A. is required by law to include objectives of common benefit in its bylaws and to report annually in a transparent way. The Group is committed to becoming carbon neutral by the end of 2035.

For further information: www.chiesi.com

Press contacts:

Elizabeth Comtois
Media Relations
Phone: (919) 334-3786
Email: Elizabeth.comtois@fleishman.com

Chiesi Group
Alessio Pappagallo

PRESS RELEASE

Press Office Manager
Tel: +39 339 5897483
Email: a.pappagallo@chiesi.com

PP-G-0766 V1.0