



## ICON Supports Pfizer and BioNTech on the Investigational COVID-19 Vaccine Trial

January 4, 2021

### *Trial capabilities key to enabling agility and speed in global study involving 44,000 subjects*

DUBLIN--(BUSINESS WIRE)--Jan. 4, 2021-- **ICON plc, (NASDAQ:ICLR)**, a global provider of outsourced drug and device development and commercialisation services to the pharmaceutical, biotechnology and medical device industries and government and public health organisations, today announced it provided clinical trial services to the Pfizer (NYSE:PFE) and BioNTech SE (Nasdaq: BNTX) investigational COVID-19 vaccine programme. Pfizer and BioNTech were the first to announce positive efficacy results from a Phase 3, late-stage study of a COVID-19 vaccine and to receive Emergency Use Authorization in individuals 16 years of age or older from the U.S. Food and Drug Administration.

ICON mobilised a large global team of therapeutic and operational specialists to partner on the implementation of Pfizer's and BioNTech's strategic plan and framework for the monitoring of the trial, which included a high level of remote clinical monitoring and source data verification in addition to on-site monitoring, safeguarding data quality and integrity in the evolving pandemic environment. The team combined the benefits of full service and functional service provider clinical operating models to increase efficiency and ensure rapid study start-up.

ICON worked with 153 sites in the US, Europe, South Africa and Latin America to ensure the recruitment of more than 44,000 trial participants over a four month period. ICON provided site training, document management and operational support for patient Informed Consent Form review, coordinated eConsent in most countries, and assisted with clinical supply management services. Achieving the unprecedented trial timelines, while maintaining high standards of quality, undertaken in response to the pandemic required collaboration and strong communication between the ICON and companies' project teams.

Steve Cutler, CEO at ICON plc, commented, "We are proud to have supported Pfizer and BioNTech on one of the largest and most expeditious randomised clinical trials ever conducted, and to have helped accelerate their mission to develop the world's first safe and effective investigational vaccine for COVID-19. Through close collaboration with Pfizer and BioNTech, we used a full suite of innovative approaches and technologies to support achieving fast site activation, patient recruitment and remote and on-site monitoring, which enabled us to meet accelerated study timelines on the way to delivering high quality data for regulatory approval. I'd like to thank all of the study team members from Pfizer, BioNTech and ICON who collaborated so well. This trial has demonstrated the benefits of a strong sponsor/Clinical Research Organisation partnership and has redefined industry expectations in terms of trial management and speed, while never compromising safety, quality and integrity. We look forward to applying the experience gained over the past year to future trials."

In September 2020, ICON was awarded the Best Clinical Research Organisation (CRO) at the Vaccine Industry Excellence (ViE) Awards for the third time. ICON was awarded ViE Best CRO in 2017 and 2014, and has been named as a finalist every year since 2011, demonstrating a long history of excellence in vaccine research.

ICON has provided clinical trial services to Pfizer over the past 30 years and formed a strategic relationship with the company in 2011, to provide global expertise in the planning, execution, management and conduct of clinical trials.

### **About ICON plc**

ICON plc is a global provider of outsourced drug and device development and commercialisation services to pharmaceutical, biotechnology, medical device and government and public health organisations. The company specialises in the strategic development, management and analysis of programs that support clinical development - from compound selection to Phase I-IV clinical studies. With headquarters in Dublin, Ireland, ICON employed approximately 15,250 employees in 94 locations in 40 countries as at September 30, 2020. Further information is available at [www.iconplc.com](http://www.iconplc.com)

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