

# CELL & GENE THERAPY DEVELOPMENT SOLUTIONS

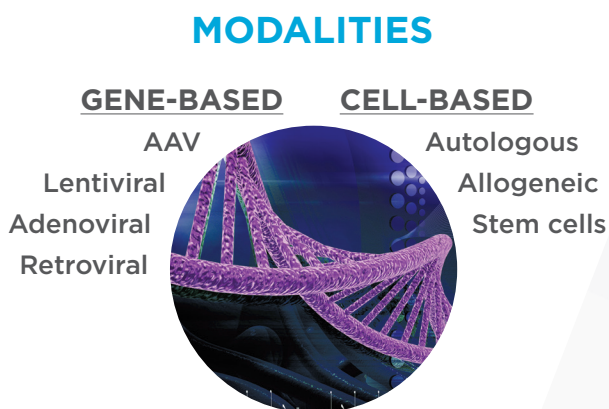
EXCEPTIONAL SCIENCE, TIMELY ANSWERS AND ADDED VALUE

## DID YOU KNOW

that one of the leading causes of delay in a drug or therapeutic candidate achieving marketing authorization is due to **CMC deficiencies associated with analytical testing**<sup>1</sup>? Consider that the average additional time to obtain marketing authorization with this type of delay can be **up to a year or longer**<sup>1</sup> and the commensurate drop in asset value can be **up to 20% or more**<sup>2</sup>.

## TRUSTED INSIGHTS

to reduce the risk of CMC analytical testing deficiencies originate from **scientific expertise and experience**



**20+**

**Years** supporting the analytical development and testing of cell and gene therapy products

**7**

**Modalities** of cell and gene therapy product experience

**15+**

**Cell and Gene Therapy Products** supported annually

**CO-AUTHOR**

In a leading **peer-reviewed publication**<sup>3</sup>

## HELPING YOU

to make better choices of how you manage and what you spend to support your product's lifecycle

- ▶ **Analytical control strategy** and plan to align with product CQAs
- ▶ **Method development**, phase appropriate qualification and validation (GMP/ICH)
- ▶ **Analytical testing** (including in-process): safety, identity, strength, quality and purity
- ▶ **Biodistribution** to target and non-target tissues
- ▶ **Routine global lot release and stability testing** under commercial GMP conditions

1. FDA Complete Response Letter Analysis: How 51 Companies Turned Failure into Success (FDA News Report)

2. Estimate based on rNPV model

3. N. Carriglio, *et al.* (2017) Good Laboratory Practice Preclinical Safety Studies for GSK2696273 (MLV Vector-Based *Ex Vivo* Gene Therapy for Adenosine Deaminase Deficiency Severe Combined Immunodeficiency) in NSG Mice. *HUMAN GENE THERAPY CLINICAL DEVELOPMENT*, VOLUME 28 NUMBER 1

# SMARTER DECISIONS & ADDED VALUE

from **timely answers and novel solutions** delivered via global capabilities across the drug development continuum and beyond

- ▶ BioCMC analytical solutions
- ▶ Safety and efficacy pharmacology
- ▶ Toxicology
- ▶ Drug metabolism
- ▶ Bioanalysis
- ▶ Clinical development
- ▶ Clinical testing, including biomarkers and CDx
- ▶ Regulatory
- ▶ Consulting and Partnering
- ▶ Informatics
- ▶ Commercialization



## GLOBAL NETWORK

**Nonclinical and clinical facilities** offering development solutions in support of submissions

## GLOBAL PROJECT MANAGEMENT

**As a single point of contact** that actively monitors and reports on your project from proposal to invoice

# 3

**GMP Analytical Development and Testing Labs** across the UK and US†

# BIOCMC ANALYTICAL TESTING CAPABILITIES

Exceptional science to help identify, assess and demonstrate control over your product's Critical Quality Attributes

- ▶ Sterility
- ▶ Endotoxin
- ▶ Bioburden
- ▶ Sub-visible particles
- ▶ Mycoplasma/spiroplasma
- ▶ Mycobacterium
- ▶ Aggregates
- ▶ Appearance
- ▶ pH
- ▶ Osmolality
- ▶ Extractable volume
- ▶ Container integrity
- ▶ Virus identification
- ▶ Intact Mass (LC-MS)
- ▶ Western Blot
- ▶ Infectious titre
- ▶ Replication competent virus/AAV
- ▶ Genomic titre
- ▶ Capsid titre
- ▶ Cell-based ID and potency
- ▶ Concentration
- ▶ Biodistribution
- ▶ Genetic stability
- ▶ Empty vs full capsids
- ▶ Purity
- ▶ GMP & non-GMP stability and release

† The York, UK BioCMC Analytical Testing Lab is scheduled to achieve GMP compliance in early 2018. The Harrogate UK and Greenfield, US Labs are GMP compliant and routinely inspected by the FDA & MHRA.

Learn more about our drug development solutions at [www.covance.com](http://www.covance.com)

Covance Inc., headquartered in Princeton, NJ, USA is the drug development business of Laboratory Corporation of America Holdings (LabCorp). COVANCE is a registered trademark and the marketing name for Covance Inc. and its subsidiaries around the world.

The Americas + 1.888.CO Vance (+1.888.268.2623) + 1.609.452.4440

Europe / Africa + 00.800.2682.2682 +44.1423.500888

Asia Pacific + 800.6568.3000 +65.6.5686588

© Copyright 2017 Covance Inc. SSBPH001-1217

**COVANCE**  
SOLUTIONS MADE REAL®