ANNE-VIRGINIE EGGIMANN, M.Sc.
CHIEF REGULATORY OFFICER

Executive leader with significant experience in the development of innovative medicinal products and a track record in bringing orphan drugs, gene therapy and oncology products from preclinical stage of development to marketing authorization for the benefit of patients.

Prior to joining bluebird bio in 2011, over the course of a decade, contributed to the global growth of Voisin Consulting Life Sciences, a regulatory consulting firm, leading many development and registration projects partnering with both US and European biotech companies.

During tenure at bluebird bio, led regulatory team that ultimately received marketing approvals for four gene therapies in severe genetic diseases and oncology: Zynteglo for beta-thalassemia, Abecma for multiple myeloma (in partnership with Celgene/BMS), Skysona for cerebral adrenoleukodystrophy (CALD), and more recently after my departure, Lyfgenia for sickle cell disease.

Led team to prepare for two precedent-setting FDA Cellular, Tissue and Gene Therapies Advisory Committee meetings for Skysona and Zynteglo: June 9 & 10, 2022 - Unanimous positive votes.

Actively engaged for the past 20+ years in shaping the regulatory science and policy environment for cell and gene therapy.

CURRENT POSITION

Tessera Therapeutics, Inc. – Somerville, MA, USA - August 2022 to present
Chief Regulatory Officer

EMPLOYMENT HISTORY

bluebird bio, Inc. – Cambridge, MA, USA – June 2021 to August 2022
Chief Regulatory Officer

bluebird bio, Inc. – Cambridge, MA, USA – January 2019 to May 2021
Senior Vice President – Regulatory Science

bluebird bio, Inc. – Cambridge, MA, USA – August 2013 to January 2019
Vice President – Regulatory Science

bluebird bio, Inc. – Cambridge, MA, USA – September 2011 to July 2013
Senior Director – Regulatory Science

In November 2021, bluebird bio split into 2 companies: bluebird bio focused on severe genetic diseases, and 2seventy bio focused on oncology.

Key projects at bluebird bio:

- European Union (EU) marketing authorization for Zynteglo for the treatment of patients with β-thalassemia with non β^0/β^0 genotypes in 2019 (withdrawn in 2021 for business reasons); US Biologics License Application (BLA) for Zynteglo for the treatment of adult and pediatric patients with β-thalassemia who require regular red blood cell transfusions in 2022
- Collaboration with Celgene/BMS leading to the BLA approval of Abecma (a chimeric-antigen receptor T cell product) for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody in 2021

- EU marketing authorization for Skysona in 2021 (withdrawn same year for business reasons); submission of BLA approved in September 2022 to slow the progression of neurologic dysfunction in boys 4-17 years of age with early, active CALD
- Participation in European Medicines Agency Adaptive Pathways Pilot
- Initial New Drugs (INDs) and Clinical Trial Applications (CTAs) for 5 gene therapy products consisting of hematopoietic stem cells or T-cells genetically modified ex vivo with lentiviral vector
- INTERACTs, pre-INDs, End-of-phase 2, and pre-BLA meetings with FDA; Scientific advice and pre-MAA meetings in Europe, including joint meetings with patients and Health Technology Assessment (HTA) bodies
- Regenerative Medicine Advanced Therapy (RMAT) and Breakthrough Designations, Fast Track, Orphan drug designations, Pediatric Investigation Plans (PIPs)

Regulatory policy activities as Industry Representative while at bluebird bio:

Chair of the Regulatory Committee of the Alliance for Regenerative Medicine (ARM) - 2015 to 2018
Successful advocacy to:

- Revise role of NIH Recombinant DNA Advisory Committee (RAC) for public review of gene therapy protocols
- Create of RMAT designation in collaboration with the FDA Office of Tissues and Advanced Therapy (OTAT); legislative language included in 21st Century Cures Act (Section 3033)
- Formalize INTERACT meetings (previously "pre-pre-IND") and create CATT meetings to support early discussions on CMC issues for cell and gene therapy products
- Revise GMO regulations for investigational gene therapy products in Europe

Participation as Alternate negotiator in PDUFA VII negotiations for Biotechnology Innovation Organization (BIO) with PhRMA and FDA – 2020-2021

- Contributed to creating FDA Chemistry, Manufacturing, and Controls Development and Readiness Pilot (CDRP) Program.

Co-Chair of the Regenerative Medicine Committee of BIO – 2020 to present

- Platform approaches, white-paper and active participation in working group
- Led discussions to advocate for improvements in management of clinical holds by OTAT

Member of ARM Regulatory Advisory Group – 2018 to present

EMPLOYMENT HISTORY (CONTINUED)

Voisin Consulting, Inc. Life Sciences (VCLS) – Cambridge, MA, USA – 2009 to Sept. 2011
Executive Director – Drugs & Biologics Projects and Global Business Development
Management of US and Swiss Teams

Voisin Consulting, Inc. – Cambridge, MA, USA – 2008-2009
General Manager - Project Director, Drugs and Biologics - Global Business Development Lead

Voisin Consulting Sarl – Lausanne, Switzerland –2006-2008
General Manager - Project Director Drugs and Biologics

Voisin Consulting SARL - Paris, France
Project Director — 2003-2006
Consultant – 2000-2003

Key projects at VCLS:

- Assisted biotech companies in the design and implementation of global regulatory strategies - drugs, biologics, including cell & gene therapies
- EU Marketing authorization of small molecule for the treatment of acute promyelocytic leukemia (APL) - 3rd orphan MAA in the EU - 2001
- Contributed to creation of European Commission Advanced Therapy Medicinal Products (ATMP) Regulation with EuropaBIO (first regulatory framework for cell & gene therapy in Europe)
- EU marketing authorization for first monoclonal antibody to treat Paroxysmal Nocturnal Hemoglobinuria (PNH) – 2007
- EU marketing authorization for immunomodulating treatment of high-grade non-metastatic osteosarcoma in patients aged between 2 and 30 years; conversion to NDA submission - 2009
- Development and EU marketing authorization for first advanced therapy product approved in the EU (ChondroCelect for the treatment of cartilage defect) - 2009
- Long-term projects with biotech companies in Cambridge, MA: small molecule for the treatment of cystic fibrosis leading to EU registration in 2012, early development of siRNA for the treatment of hereditary transthyretin-mediated amyloidosis
- Led several first in human projects and successful end of phase 2 interactions with regulators
- Scientific Advice, Protocol Assistance, national regulatory agency meetings and Briefing Meetings with EMEA; pre-IND meetings (Office of Cell, Tissues and Gene Therapy [OCTGT], Division of Gastroenterology and CNS Division); meetings with FDA Center for Veterinary Medicine
- Orphan Designations; Pediatric Investigational Plans; Risk Management Plans
- Contributed to creation of Swiss and US Offices of VCLS
- Registration of a new formulation of diclofenac (UK) – 2006
- Participated in creation of QA system (ISO 9001); created regulatory intelligence function

EMPLOYMENT HISTORY (CONTINUED)

CH2M HILL – Santa Ana, California, USA – 1999-2000
Environmental Engineer – Energy, Environment and Systems Business Group

- Managed compliance study for Aerospace NESHAP for Boeing facilities
- Managed information system for back-flow prevention devices for US Air Force drinking water
- Managed data analysis and reports on soil remediation for the Los Angeles Harbor Department
- Risk Management Plans for Water Treatment Plants – Off-site consequence analysis
- SCAQMD various permitting applications; Rule 1401 analysis (Air Toxics Health Risk Assessment)

PARSONS Engineering Science - Pasadena, California, USA
Staff Engineer - Air Quality Department – 1997- 1999

- Air emission inventories and Air Dispersion Modeling for Environmental Impact Reports
- Reports on Impact of EPA new PM2.5 and Ozone standards, and alternative to medical incinerators
- EPA Risk Management Plans and OSHA Process Safety Management Plans for Water Treatment Plant
- EPA Risk Based Corrective Action project for contaminated soil with chlorohydrocarbons

EDUCATION

1995 – 1997
University of California Los Angeles (UCLA) - School of Public Health
Master of Science - Environmental Health Sciences

1991 – 1995
California Institute of Technology (Caltech) - Pasadena, California
Bachelor of Science - Chemical Engineering

1987-1990
Lycée François Magendie - Bordeaux, France
Baccalauréat – Life Sciences – « Mention Bien »

RESEARCH EXPERIENCE

1995 - 1997
Research Associate - UCLA - Environmental Health Sciences - Dr. John Froines (Chicago 7)

- Research on toxicity of cleaning products containing glycol ethers
- Thesis referenced in "P2 Problem Solving" - Pollution Prevention Review - Winter 1998:125-133.
- Research Associate - UCLA - Environmental Health Sciences - Dr. Collins
- Toxicology research on teratological effect of arsenic in drinking water

1992 - 1995
Research Assistant - Caltech Chemical Engineering Department - Dr. Frances Arnold (Nobel prize in Chemistry in 2018)

- Produced and purified protein cytochrome C from Saccharomyces Cerevisiae yeast
- Bio-engineered Eschericia Coli to produce specific RNAse
- Expertise in liquid chromatography (ion exchange, size exclusion and HPLC)

EXTRACURRICULAR ACTIVITIES & INTERESTS

Running, Swimming, Skiing, Hiking, Movies, Novels
Varsity Water Polo and Swim Team – Caltech