



# A Journey Through the Biopharmaceutical Industry

Ken Miller

Diverse Voices: Breakfast Chats

WCBP 2024

January 24, 2024



**B**:OMARIN®

***Disclaimer:** “This presentation reflects the views of the presenter and should not be construed to represent those of BioMarin Pharmaceutical, Inc.”*



## **Ken Miller**

Director, Global Stability & CMC Analytical Data Management  
BioMarin Pharmaceutical, Inc.

# Beginning in Academia – 1985 to 1996



B.S. in Biochemistry



Ph.D. in Biological Sciences



Postdoctoral Fellow in  
Dept. of Microbiology

# Moving Beyond Academia – 1995 to 2004



**Bristol-Myers Squibb**

Postdoctoral Fellow,  
Dermatology Drug Discovery



**BIACORE**

Application Scientist &  
Technical Support Manager

# Building a Career in Biopharma – 2004 to Present



# Developing Assays for Lot Release & Characterization of Clinical Products

## **WCBP 2007**

“Development of a Host Cell Protein Assay Using Surface Plasmon Resonance Technology”

## **WCBP 2008**

“Development of a Novel Surface Plasmon Resonance Biosensor Assay for the Simultaneous Characterization of Antigen Binding and Fc Receptor Binding”

## **WCBP 2010**

“Development and Qualification of an SPR-Based Assay for Lot Release and Stability Testing”

# Leading a CMC Analytical Team During Development

 **Beyfortus**<sup>™</sup>  
(nirsevimab-alip) | 50 mg  
100 mg  
Injection

# Managing Bioassay Life Cycle Post-Licensure





# Fighting a Global Pandemic – COVID-19



# Ensuring Shelf-Life of Marketed Products

 **ALDURAZYME**<sup>®</sup>  
(LARONIDASE)

 **Naglazyme**<sup>®</sup>  
(GALSULFASE)

 **KUVAN**<sup>®</sup>  
(sapropterin dihydrochloride)  
Tablets or Powder for Oral Solution

 **VIMIZIM**<sup>®</sup>  
(elosulfase alfa)

 **Brineura**<sup>®</sup>  
(cerliponase alfa)

 **Palynziq**<sup>®</sup>  
(pegvaliase-pqpz) Injection

 **VOXZOGO**<sup>™</sup>  
(vosoritide) for injection

 **ROCTAVIAN**

# Developing the Next Generation – 2021 to ???



*BTEC/ENCH 664: Quality Control & Quality Assurance for Biotechnology Products*

