



BIO•PHARMA
S E R V I C E S

Our CMC Works with DNDi

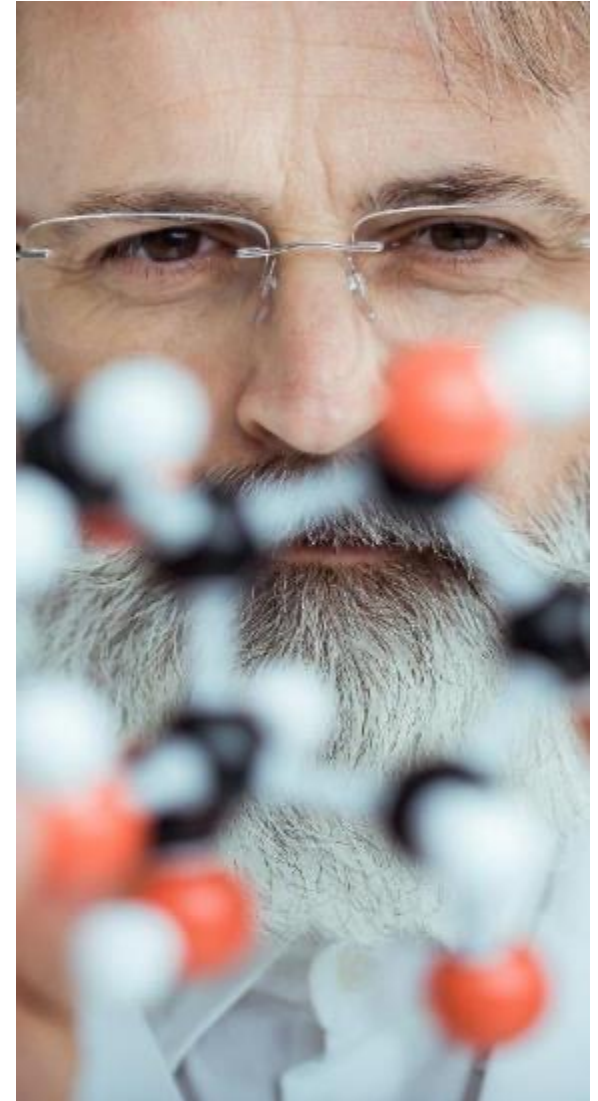
October 22, 2021

Tomomi Kimura
Ajinomoto Bio-Pharma Services, GeneDesign
SALES&TECHNICAL SUPPORT

Agenda

1 Introduction

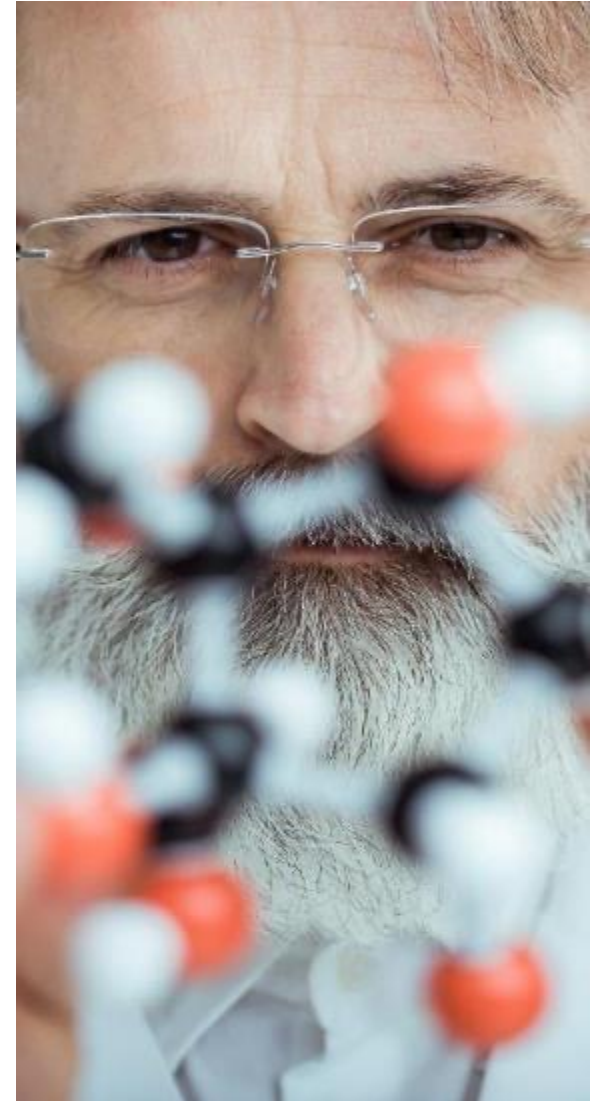
2 Works and Accomplishments with DNDi



Agenda

1 Introduction

2 Works and Accomplishments with DNDi



Ajinomoto group Shared Value(ASV)

ASV

⇒ ASV means the **A**jinomoto group creating **S**hared **V**alue

Within the Ajinomoto group, our mission is

- ✓ To contribute to the world's food and wellness
- ✓ To better lives for the future

With the above concept,
we have been working on this
project with DNDi



Ajinomoto Bio-Pharma Services



SMALL MOLECULE
MANUFACTURING



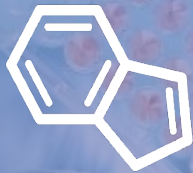
LARGE MOLECULE
MANUFACTURING



HIGH POTENCY
& ADC SERVICES



DRUG PRODUCT
FILL FINISH



OLIGO & PEPTIDE
SYNTHESIS



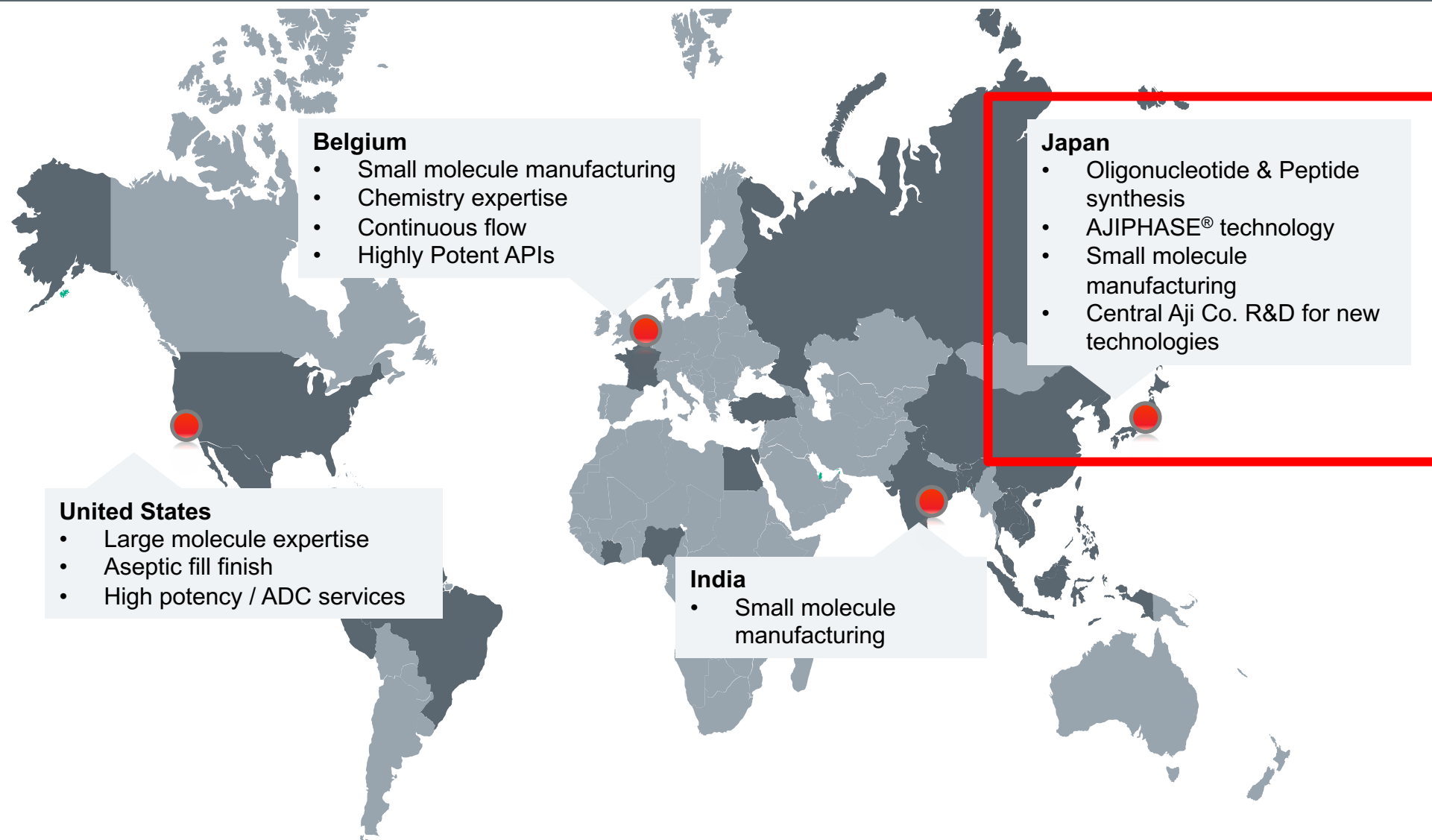
DEVELOPMENT &
SCALE UP SERVICES



PRODUCT QUALITY &
ANALYTICAL SERVICES

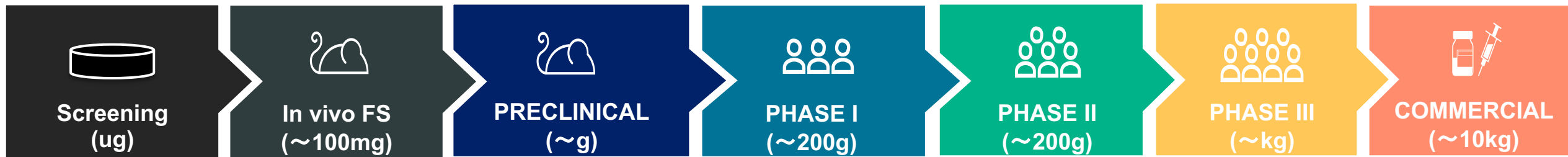
Access to a Global Collective Service Offering

Ajinomoto Co., Inc. is actively engaged in **26 countries and regions** worldwide



Oligo CDMO Services Overview

SEAMLESS SUPPLY FROM
RESEARCH TO COMMERCIAL LAUNCH



Research-use
at small/ middle scale


DRUG
SUBSTANCE


DEVELOPMENT

GLP- use Manufacturing

GMP Manufacturing

Bridging to AJIPHASE®

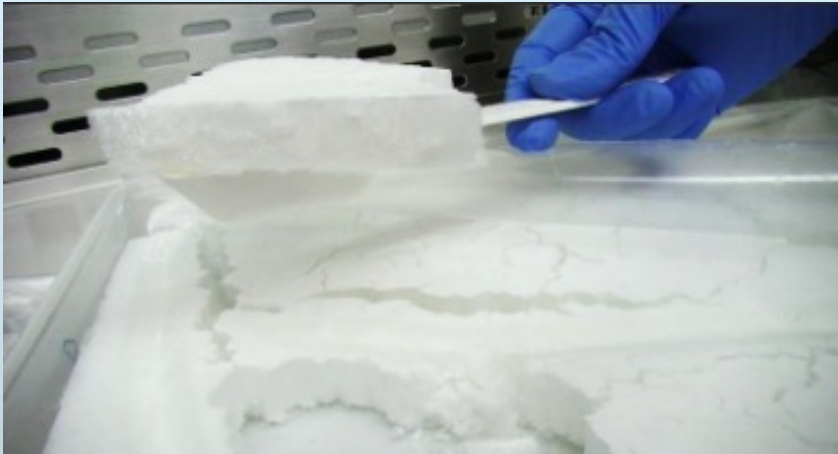
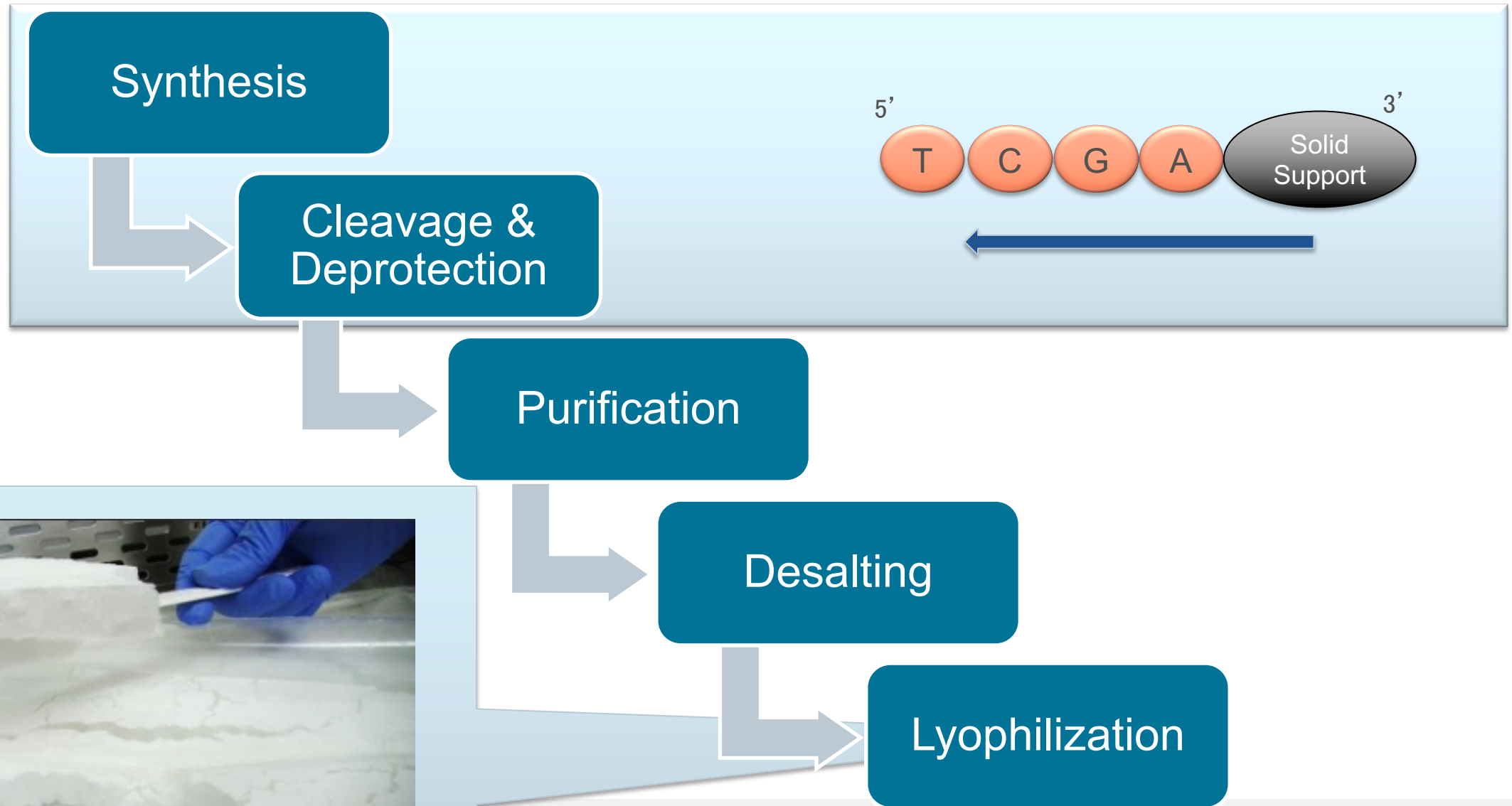
Analytical Methods - Development, Stability & Release Testing, and Validation

Comparability Studies

Process Development / Scale Up / Optimization



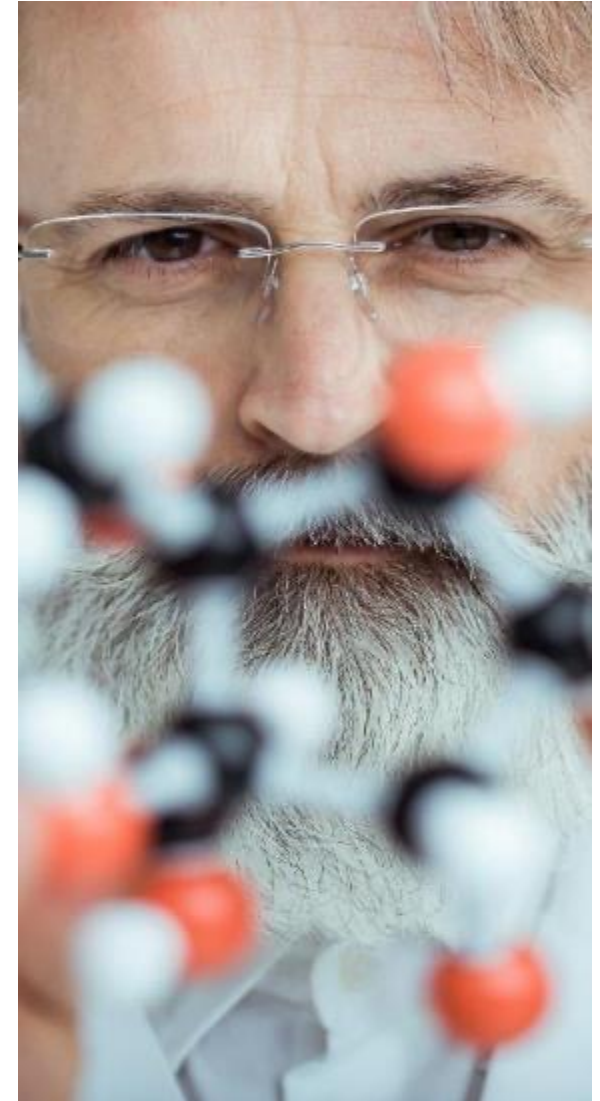
Brief Overview of Oligonucleotide Manufacturing



Agenda

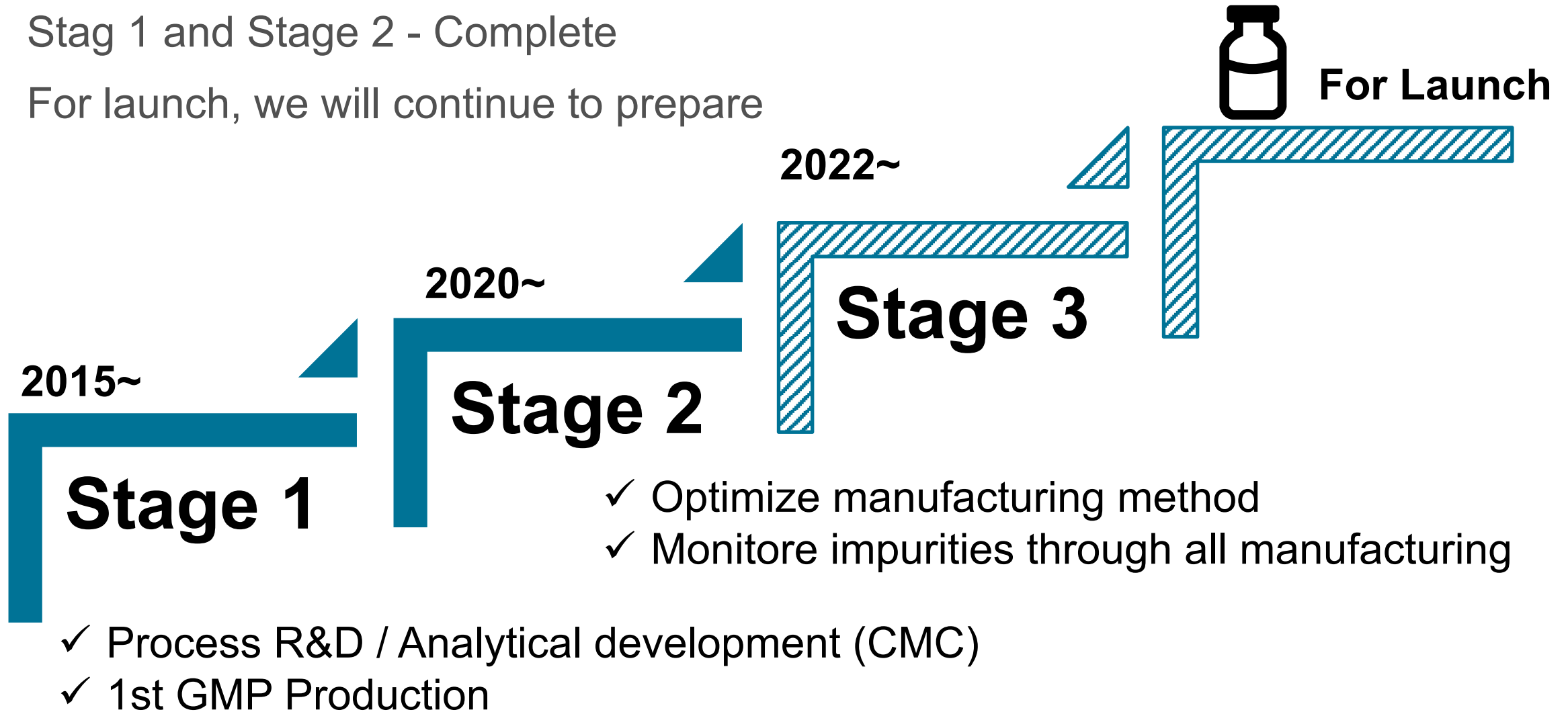
1 Introduction

2 Works and Accomplishments with DNDi



Our History with DNDi

- Stage 1 and Stage 2 - Complete
- For launch, we will continue to prepare



Accomplishment of Stage 1

Stage 1



- Process R&D for D35
 - ✓ Synthesis conditions
 - ✓ Deprotection condition
 - ✓ Purification Support & condition



Several hundred grams
GMP manufacturing

Synthesis



Cleavage &
Deprotection



Purification



Desalting



Lyophilization

Accomplishment of Stage 1

Stage 1



- Analytical Development for D35
 - ✓ Confirmation of Purity
 - ✓ Identification of Impurities
 - ✓ Confirmation of Sequence
 - ✓ Stability Program / Degradation Tests



Method validation has been done.

Accomplishment of Stage 2

Stage 2



- Improved Process Successfully
 - ✓ Scale up Synthesizer
 - ✓ Better Impurity Control
 - ✓ Turnaround Time for purification = one third.



With current Stage 2 process,
several kg /year of API can be produced

Next Stage Works for Launch

Stage 3



Manufacturing

Higher
Productivity

Confirm
Robustness

Ready for
Launch

Analysis

Change
Incomplete
Test Methods

Validation

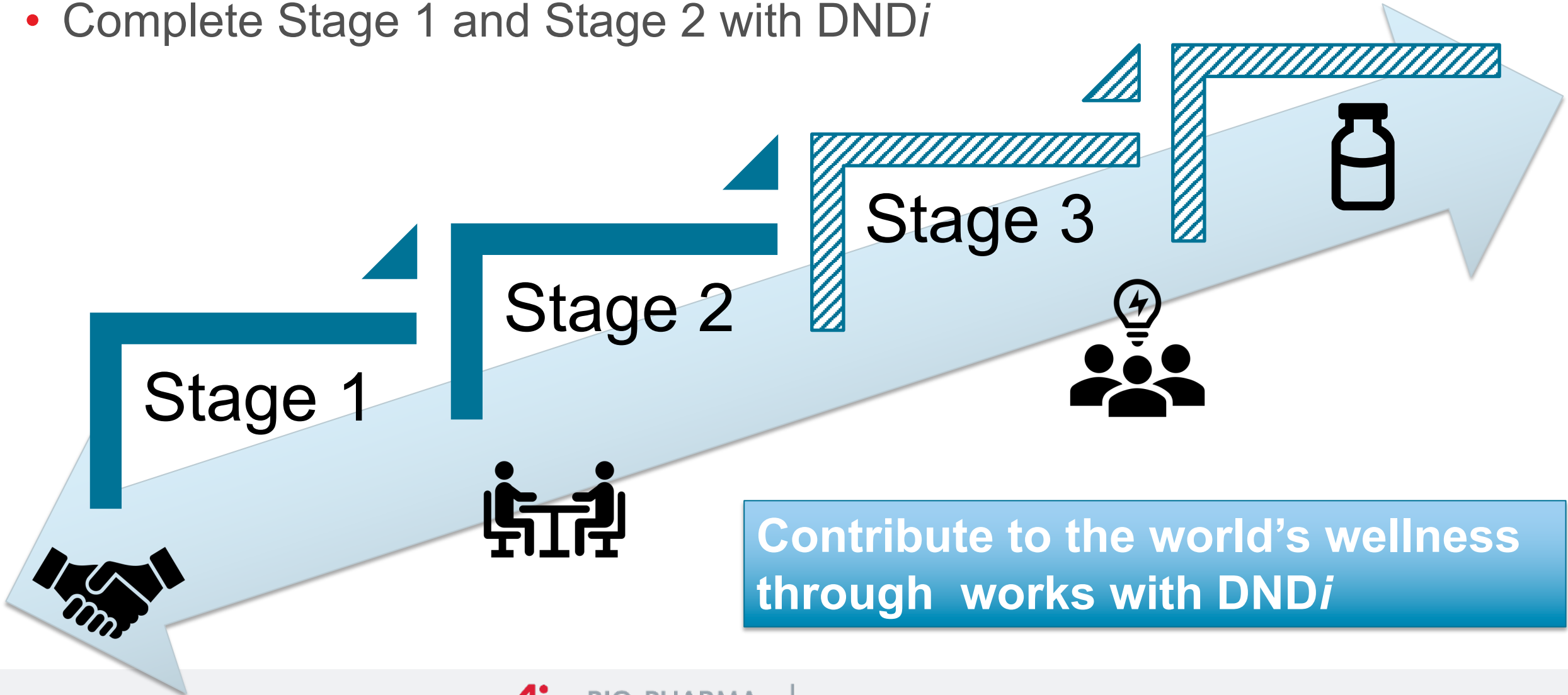
Ready for
Launch

Support

New-Drug
application

Summary

- Complete Stage 1 and Stage 2 with DNDi



**LET'S
MAKE**

A NEW FUTURE



A Responsive, Trusted, Innovative
and Reliable Partner

Global Infrastructure for Adaptive
CDMO Solutions and Support

Dedicated to Your Clinical Studies
Through Commercial Successes

Your Every Manufacturing
Challenge Embraced

**WHAT DO YOU
WANT TO
MAKE?**

**POWER
TO MAKE**



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Thank You