ACCELERATE YOUR PRODUCT DEVELOPMENT WITH ROOSTERBIO PRODUCTS AND SERVICES

LATE DISCOVERY AND R&D

- **Define product quality characteristics**
- **Find clinically relevant and scalable manufacturing system**
- **Estimate cost of goods**
- **Outline expected manufacturing process**

RUO

1M Cells

>150 Cells

>1.5E12 EVs

RoosterBio can:

- Transfer your current research protocol to RoosterBio's platform in 2D/small scale
- Support genetic engineering
- Perform MSC priming

PROCESS DEVELOPMENT AND PRECLINICAL STUDIES

- **Scale up production and ensure robust manufacturing system**
- **Refine product quality characteristics**
- **Prepare preclinical doses and tech transfer preclinical models to CRO proficient in IND enabling and tox studies using qualified materials**
- **Tech transfer manufacturing process to a qualified GMP facility with finalized manufacturing process**

DEV

10M Cells

>1.5B Cells

1E13 EVs

RoosterBio can:

- Move your process to small-scale bioreactors
- Screen GMP donors
- Scale to appropriate bioreactor size for clinical trial phase
- Finalize and transfer batch records to a GMP facility

IND APPLICATION

- **Pre-IND meeting with FDA or other regulatory authority**
- **IND file preparation 2-3 months prior to IND submission. If in the U.S., fill out RoosterBio's request for Letters of Authorization (LoAs)**
- **RoosterBio reviews and asks for the Master Files to be amended. RoosterBio provides you with LoAs**
- **Customer submits IND referencing specific Master Files**

RoosterBio can:

- Provide regulatory support by issuing Letters of Authorization allowing clients to cross-reference our Master Files for trials under the FDAs purview or by providing regulatory dossiers for trials conducted outside of the US

PHASE I

- **~20 patients/healthy volunteers**
- **Determine if there are dose-limiting toxicities**
- **Determine biodistribution of the therapy**
- **Monitor signals of potential efficacy via secondary endpoints**
- **Design and stratify Phase II Trial according to data and biomarkers via Phase I results**
- **Consider a route to Orphan Drug approval**

GMP

20M Cells

>3B Cells

>3E13 EVs

RoosterBio can:

- Provide training and technical support to assist clinical manufacturing
- Perform media comparability, bridging, and optimization studies

PHASE II

- **~50-100 patients**
- **Validate safety and spectrum of adverse events with effective dose window likely zeroed in**
- **May use interim reporting to determine go/no-go manufacturing advance to Phase III, return to Phase II, or earlier**
- **Meet with regulatory agencies to discuss large-scale studies**
- **Design Phase III Trial according to patient responders and key monitored biomarkers**

100M Cells

>25B Cells

>3E14 EVs

RoosterBio can:

- Establish a supply agreement to secure key materials for production
- Work on scaling the process if needed
- Perform media comparability, bridging, and optimization studies

PHASE III

- **~100s of patients**
- **Here, may use interim reporting for proactive go/no-go manufacturing scale up plans for post-BLA & market phase**
- **Consider prospective "off label" uses and/or new trials directed at different clinical indications or expanded patient cohorts**
- **Strategize pipeline based on successful cell tech platform**
- **Implement plans for long-term patient monitoring**

500M Cells

>100B Cells

>1E15 EVs

RoosterBio can:

- Establish or continue the supply agreement to secure key materials for production
- Work on scaling the process if needed
- Perform media comparability, bridging, and optimization studies

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