



Qprotyn's **Viscosity-Reduction** Platform for Monoclonal Antibodies

HILOPRO® Technology

Formulating mAbs for High Concentration – Low Viscosity, SubQ Delivery



www.qprotyn.com

Our Leadership Team



Qprotyn Inc. is a Delaware Corporation founded in 2021 and is an authorized distributor representing BRL.



Lynn Hartung
President



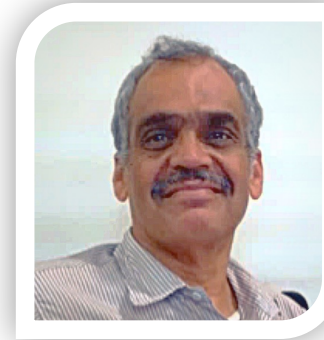
Dr. Viren Sarin
Chief Science
Officer



Janak Vadgama
BD & Marketing



Bhami's Research Laboratory is an Indian private limited company (BRL), founded in Mangalore in 2014.



Dr. Bhami Shenoy
Founder &
Chief Scientist



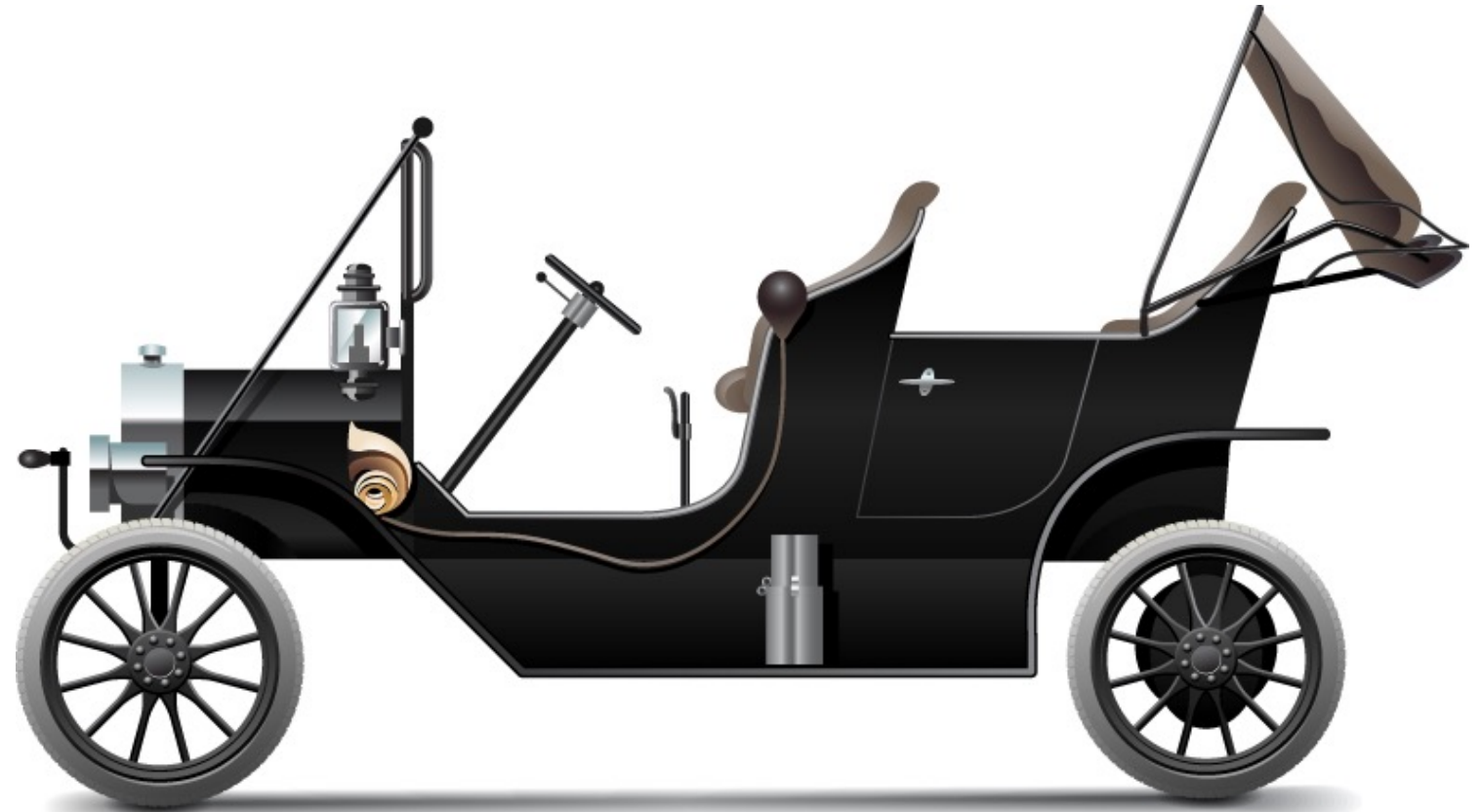
Dr. Surya Pai
Co-Founder &
CEO

Advanced mAbs ...

... same old delivery bottlenecks

Inebilizumab
Cemiplimab-rwlc
Avelumab
Sacituzumab govitecan-hzly
Naxitamab-gqgk
Elotuzumab
Margetuximab-cmkb
Reslizumab
Nivolumab
Isatuximab-irfc
Siltuximab
Teprotumumab-trbw
Ramucirumab
Ipilimumab
Alemtuzumab
Panitumumab
Cetuximab
Palivizumab ...

and many more.



Basically, even in the year 2023, mAbs can be administered any way you wish,
as long as it is IV*

The Constraint ?

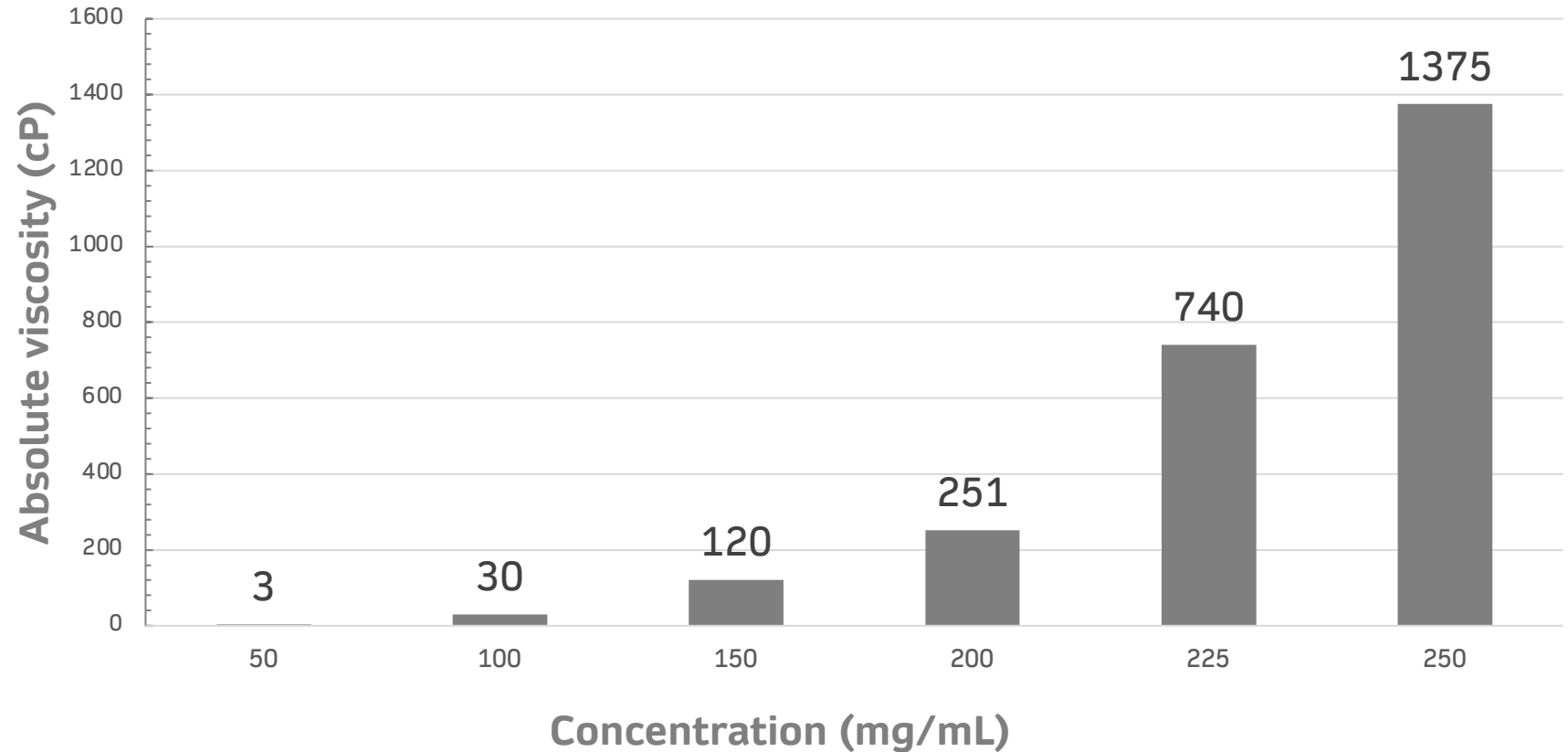
High Dose

+

High Concentration

=

High Viscosity



■ Representative Innovator mAb

Viscosity increases strikingly with higher concentration.

Qprotyn represents BRL and is the distributor of BRL's viscosity-reduction technology.

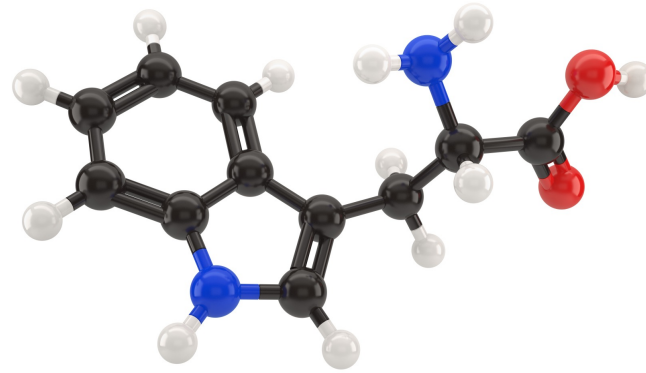
In May 2020, Bhami's Research Laboratory (BRL) was granted a US patent for an elegant new technology that has rewritten this equation:

$$\begin{aligned} & \text{High Dose} \\ & + \\ & \text{High Concentration} \\ & + \\ & \text{HILOPRO}^{\text{®}} \text{ Technology} \\ & = \\ & \text{Low Viscosity} \end{aligned}$$

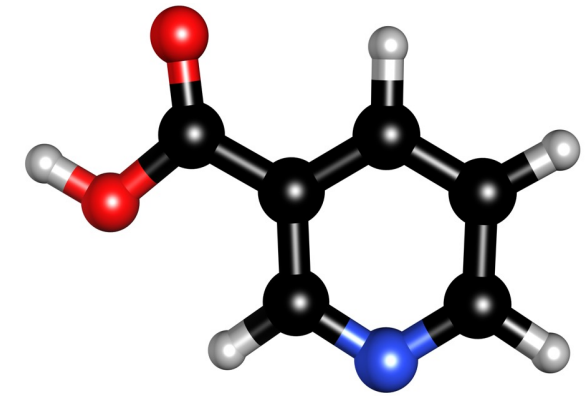
Safety Data

Safety of Excipients

Niacin and Tryptophan used **in combination** in the HILOPRO® Technology, have a No-observed-adverse-effect level (NOAEL) of **26mg/kg** of body weight for Niacin and **15.5mg/kg** of body weight for Tryptophan.



Tryptophan



Niacin

These are **GRAS excipients** that have been used **independently** in commercial parenteral nutritional supplements at high doses.

- Based on a 28-day, repeated dose toxicity study of the excipients conducted at an independent CRO*
- Additional data and the copy of the complete study can be provided under a CDA

We're not just saying that...

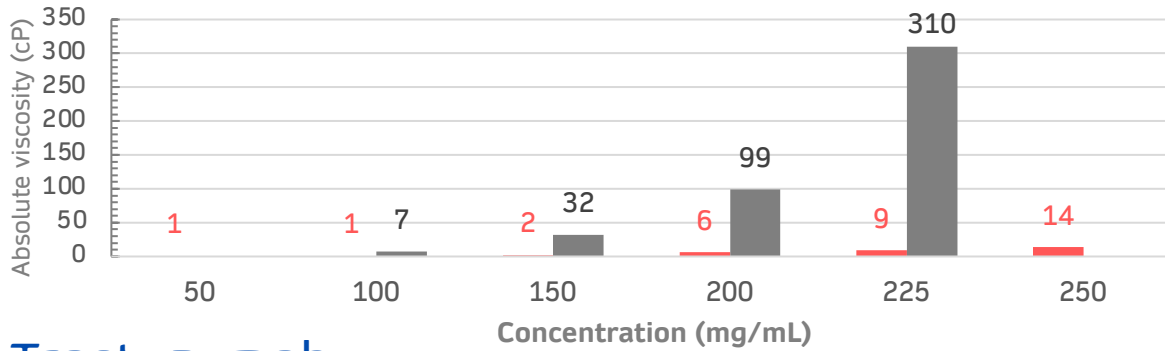
... We can prove it

Niacin and Tryptophan have never been used in the in combination for viscosity-reduction purposes.

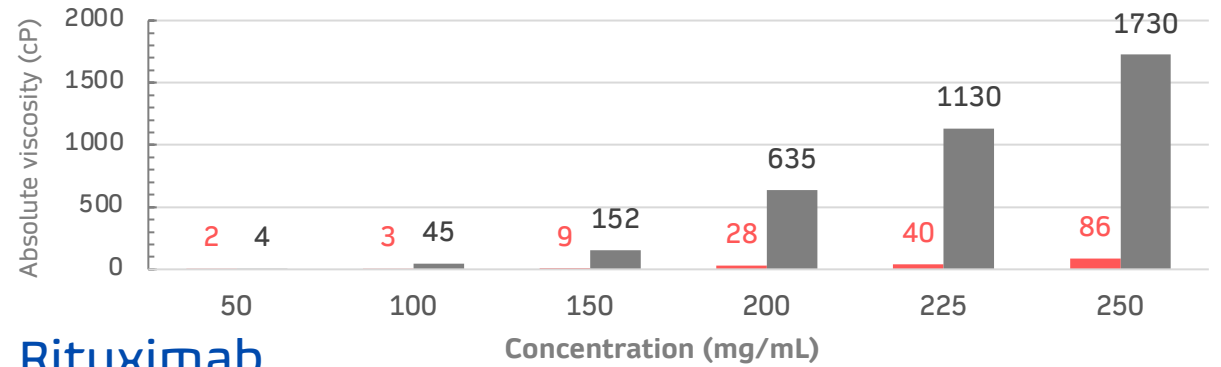
Together, they show a dramatic reduction in viscosity across all tested mAbs at roughly half of NOAEL values.

Buffer	Formulation Composition	Protein concentration (mg/ml)	Viscosity (cP at 25° C)
25 mM PHOSPHATE BUFFER, pH = 6.0	HILOPRO® EXCIPIENTS Niacin + Tryptophan	250	18
		264	20
25 mM HISTIDINE BUFFER, pH =6.0	200 mM NaCl and 250 mM Arginine	250	48
	200 mM NaCl	257	59
	250 mM Arginine	264	61
	1737 mM Proline	240	46
	250 mM Thiamine	250	48
	150 mM Nicotinamide	250	51
	690 mM Nicotinic Acid Sodium Salt	226	41
	250 mM Camphor Sulphonic Acid	229	32
	51 mM Caffeine	250	42
25 mM PHOSPHATE BUFFER, pH=6.0	Control: 25 mM Phosphate Buffer Only	250	170
		264	253

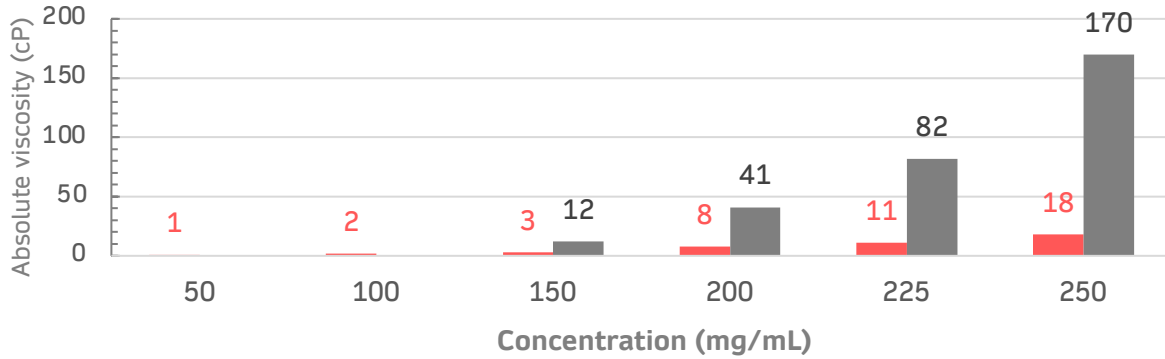
Bevacizumab



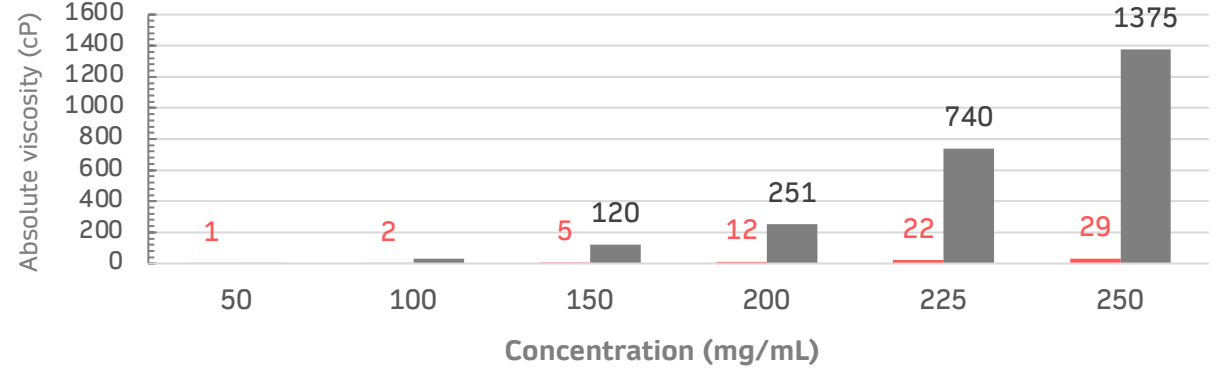
Cetuximab



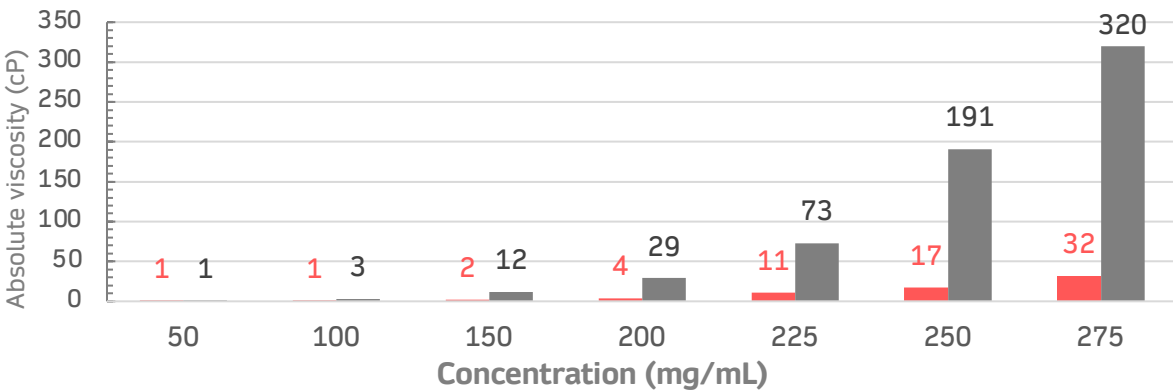
Trastuzumab



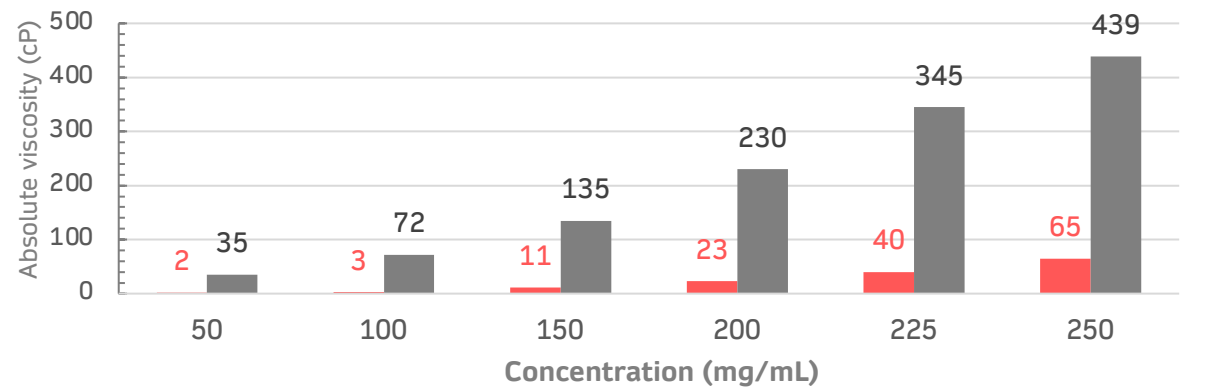
Rituximab



Human Gamma Globulin



Etanercept



It is among the best...

... stable, viscosity-reduction platform out there today

In terms of potential, HILOPRO® surpasses **all contemporary technologies** with respect to:

- Universal formulation technology for any mAb
- Platform Application
- Viscosity Reduction
- Cost
- Safety and Stability
- Turnaround time
- Ease of Manufacturing

SubQ Technology	Key Features	Major Disadvantages
High volume delivery using hyaluronidase	Degrades hyaluronan in the subcutaneous space to allow for high volume delivery	<ul style="list-style-type: none"> • Long administration time • High volume drug delivery • High cost of manufacturing • Risky self-administration for patients
Viscosity reducing excipients and formulation technologies	Use buffering agents and formulation excipients to reduce protein aggregation	<ul style="list-style-type: none"> • Not suitable as platform technologies • Potential safety and toxicity concerns • Inferior viscosity reduction abilities compared to HILOPRO®
Fluid suspension and crystallization	Use specialized particle engineering, crystallization, atomization or dehydration techniques	<ul style="list-style-type: none"> • Particles are in suspension formulations, not solutions • Not tested successfully for significant number of mAbs • High cost of manufacturing and scaling-up
High viscosity injection devices	Use high force and resistant containers to deliver high viscosity formulations	<ul style="list-style-type: none"> • Inherent stability challenges • Not tested successfully for significant number of mAbs • Increased injection site pain

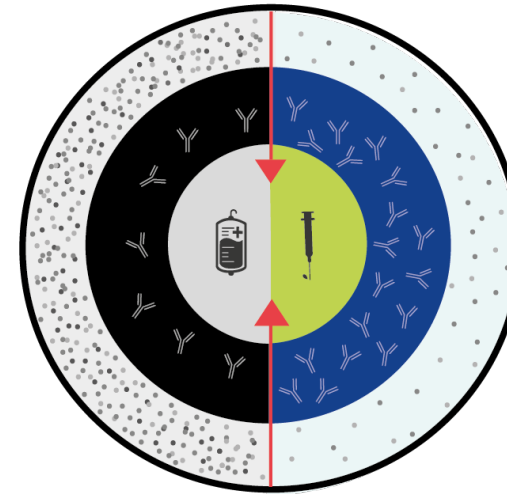
A **single formulation** technology that supports multiple dosing and delivery options

=

Greater Flexibility

+

Optimal patient convenience



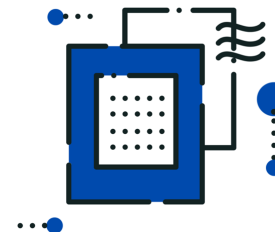
High-concentration, low-viscosity, low-volume dosing opens new delivery possibilities (while retaining existing delivery capabilities).



Intravenous



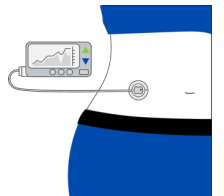
SubQ



Microneedle Patches

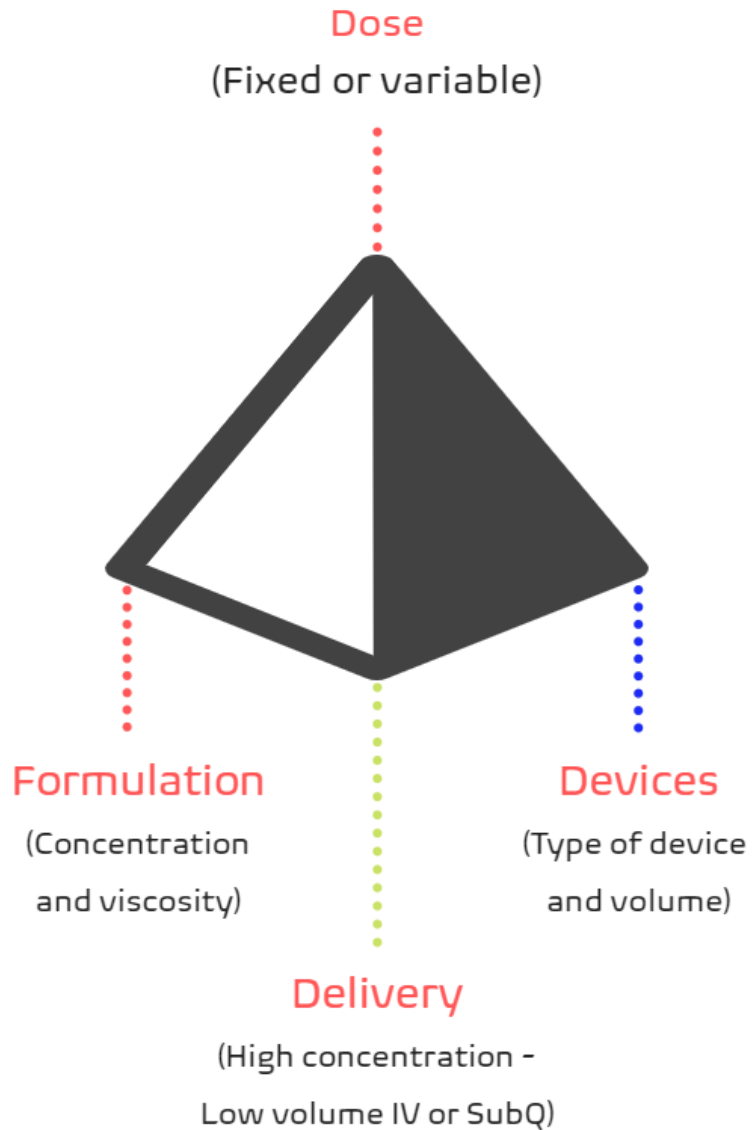


Ocular / Intravitreal



Wearable Device

IV to SubQ is a System Approach



Example	Current System	HILOPRO® System
mAb Dose	500mg	500mg
Concentration	10mg/mL	250 mg/mL
Form	Lyophilized powder for reconstitution	Solution
Delivery	IV	SubQ
Device (Vol.)	Infusion Bag (100mL)	2cc Syringe Autoinjector Wearable Device
Viscosity	NA	< 20 cP
Time to administer	30 - 90 min	< 1 min

Advantage ...

... HILOPRO®

✓ Safety

✓ Temperature stability

✓ Shelf life

✓ Efficacy

✓ Bioavailability

✓ Patient Convenience

GRAS

Excipients approved by the US-FDA and used in commercially available parenteral supplements



High concentration, low viscosity
>200mg/mL at 18cP



Confirmed stability at 4°C and 25°C under test conditions

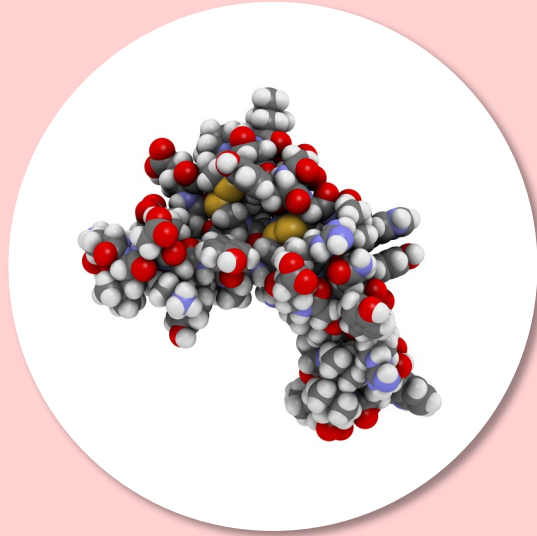


Potential for Longer Lasting efficacy as compared to IV delivery



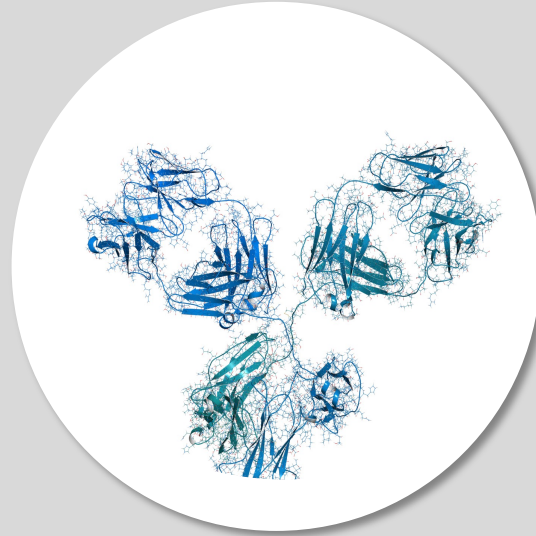
Administration time reduced from hours to minutes

Qprotyn Value Proposition



Innovator mAbs

Dosage of >500mg can be now delivered direct to SubQ instead of IV.



mAbs in Trials

mAbs in trial can be upgraded from IV to SubQ administration.



Bio - betters

First-mover advantage and differentiation value for SubQ biosimilars over dominant innovators.

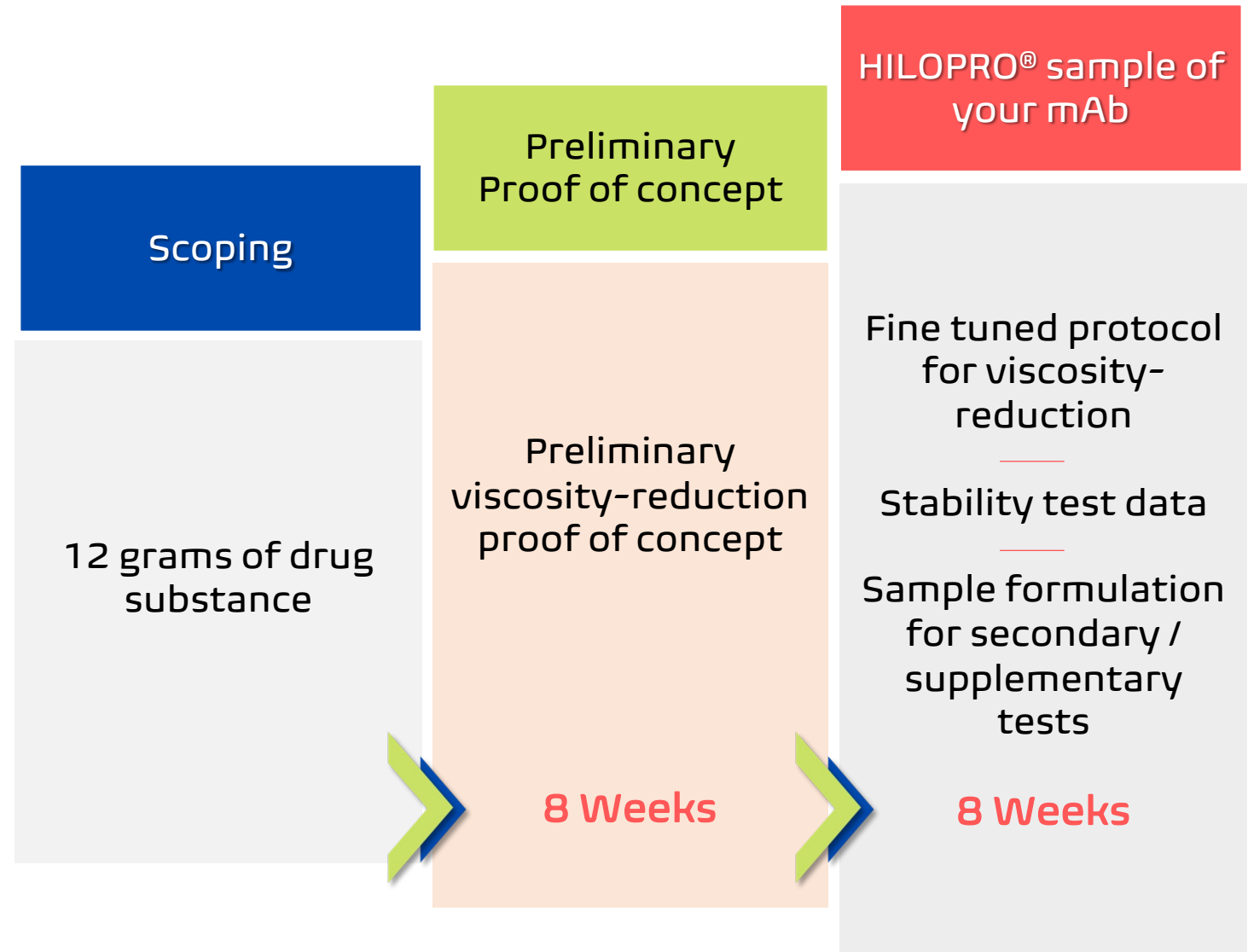
Prove it !

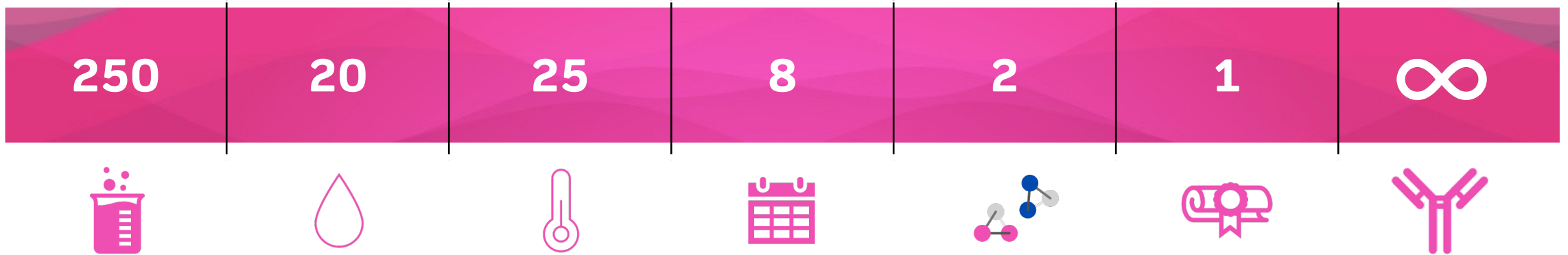
High dose mAbs and Biosimilars' pipeline

We would love to !!

Proof of Concept in
8 weeks.

HILOPRO® formulated for
further testing, in
16 weeks





Changing the world one mAb at a time.