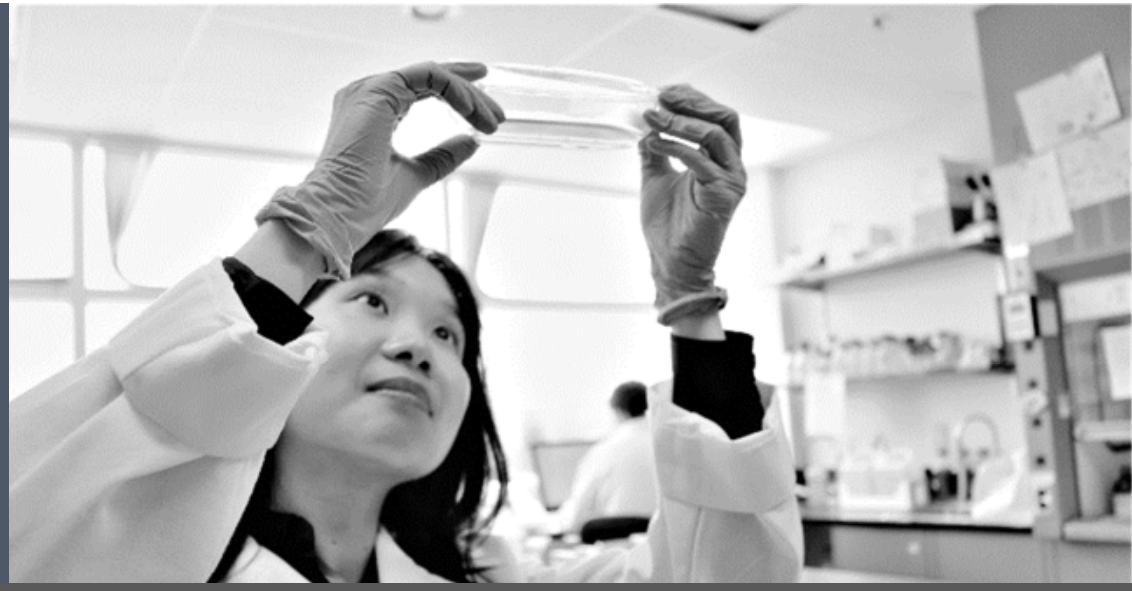
Harnessing the Power of Innate Immunity: First Line of Defense Against Viral Infection

Qu Biologics has developed a transformative first-in-class immunotherapy platform, Site Specific Immunomodulators (SSIs), that arms our first line of defense against infectious and non-infectious threats



Addressing the Need for Rapid Response to Emerging Novel Infections

- **Rapid** application in emerging viral or bacterial pandemics
- **Broad** application across a wide range of novel bacterial or viral pathogens
- **Safe** and **targeted**
- **Prophylactic** and **therapeutic** application

Innate Immunity/SSIs: Important Role in Novel Viral Infections

- Innate immunity is our body's **first line of defense** against viral infections
- Innate immunity is particularly important in novel viral infections in which there is **no adaptive immune memory** or antibodies to the novel virus
- Reduced innate immunity in the elderly, immunosuppressed, smokers and in people with chronic co-morbidities leaves them at high risk for COVID-19 morbidity/mortality
- QBKPN is designed to safely and effectively **optimize innate immune function** in the lungs including barrier function, enhancing the ability to prevent, clear and fight COVID-19 infection
- SSIs have a very good safety profile and thus, can be used **prophylactically** to prevent COVID-19 infection or **therapeutically** to treat COVID-19 infection

Limitations of Vaccines and Anti-viral Therapies

There are **four important limitations** of standard vaccines in an emerging viral pandemic:

1. Standard vaccines are **highly specific** and thus are effective for only a **single viral strain**
2. It takes a **minimum of 1 year** to develop a standard vaccine to a novel viral strain and make it broadly available, by which time the pandemic has largely taken its course
3. It is challenging to create a successful vaccine against some viruses, including coronavirus
4. Viruses, including coronavirus, can **mutate**, rendering a vaccine developed for it ineffective

There are **three important limitations** of anti-viral therapy in an emerging viral pandemic:

1. Existing anti-viral therapies may not be effective against novel viral strains
2. It takes a **significant time period** to assess the use of existing anti-viral therapies against a novel viral strain and a longer time period to develop new anti-viral therapies against novel viral strains
3. Anti-viral therapies can have significant side-effects/toxicity and thus, may not be applicable for prophylactic use

SSIs are **uniquely** positioned to be implemented at the time of **first emergence** of a novel viral strain to be used both **prophylactically and therapeutically**

Advantages of Qu's SSIs in Emerging Viral Pandemics

- Qu's SSI Platform:
  - **Clinic ready** – more than 360 patients in four Phase 2 studies
  - **Strong safety** profile
  - GMP cell bank in place and **EMA-approved CMO ready to produce**
  - Easy **self-administration**
  - Can be used both **prophylactically and therapeutically**
  - Applicable to **any viral or bacterial pathogen** regardless of past exposure
- Qu's lung-targeted SSI, QBKPN, **primes, mobilizes and recruits** innate immune cells, the **body's first line of defense** against infection, to the **lungs**
- By preventing morbidity and mortality in high risk groups, QBKPN may obviate the need to socially isolate everyone, thus, limiting the economic impact of a pandemic
- Once QBKPN SSI is approved for the prevention and treatment of viral infection, it can be **deployed immediately** in future emerging novel pandemics for any viral or bacterial infection

SSI Platform

Qu Biologics' IP is based on the discovery that acute infection (or the SSI platform) stimulates an **organ-specific recruitment** of **activated innate immune cells** targeted to the organ in which the bacterial species is **endogenous.** SSIs activate innate immunity in the targeted organ, enabling the prevention and treatment of novel bacterial or viral infections to which the immune system has not been previously exposed.

While standard vaccination establishes adaptive immune memory, Qu's SSIs, derived from inactivated bacteria, are **designed to train innate immune function** and **direct** organ-specific recruitment of these activated innate immune cells to **clear pathogens** (viral, bacterial and/or fungal) and restore a healthy **microbiome** in the targeted organ.

COMPOSITION

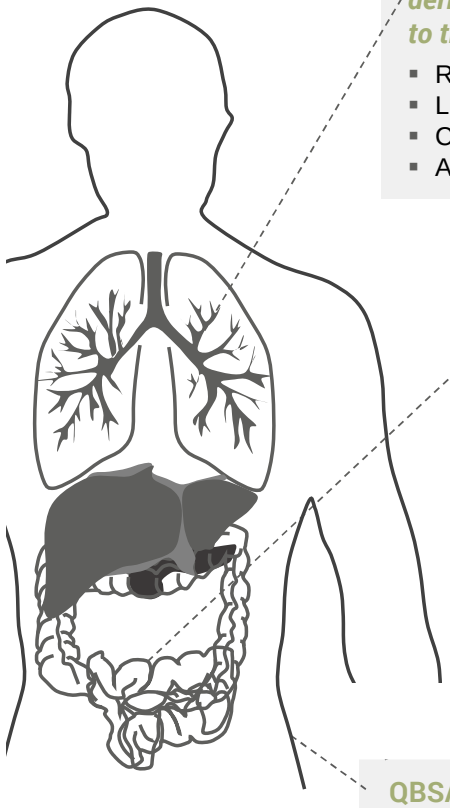
- Each organ-specific SSI, derived from an inactivated pathogenic serotype of a single bacterial species that is an endogenous common cause of infection in the targeted organ
- SSIs are made from **inactivated** bacteria and thus, do not cause infection

ADMINISTRATION

- SSIs are **self-administered** by **subcutaneous injection**

MECHANISM

- SSIs safely recruit activated innate immune cells to the targeted organ through **hematopoiesis**, **trained innate immunity**[1] and **organ specific chemokine release**
- The SSI effect stimulates the critical immunological pathways important for the prevention and resolution of infection in the **targeted organ**



QBKPN (Lung)
derived from Klebsiella pneumoniae to treat:

- Respiratory tract infection
- Lung cancer
- COPD
- Asthma

QBECO (GI)
derived from Escherichia coli to treat:

- GI infection
- Colon cancer
- Pancreatic cancer
- Inflammatory Bowel Disease
  - Crohn's disease
  - Ulcerative colitis

QBSAU (Skin, Soft Tissue, Bone)
derived from Staphylococcus aureus to treat:

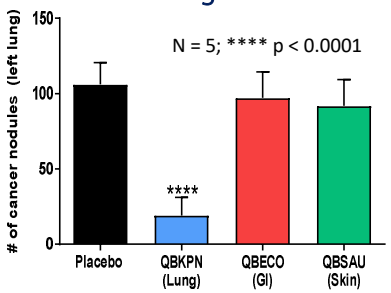
- Skin infection
- Melanoma
- Breast cancer
- Bone cancer
- Autoimmune arthritis (e.g., RA)

[1]Netea *et al.* 2016. Science **352**(6284)

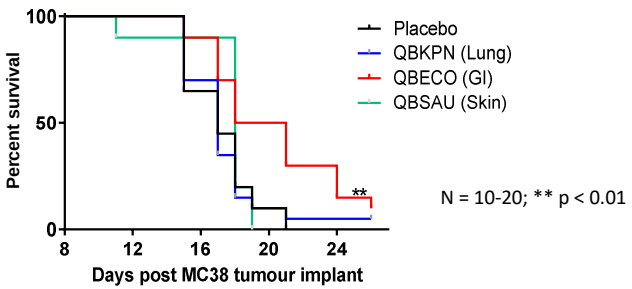
Site Specificity: Organ-Targeted & Broadly Applicable

- Only the SSI designed to target the specific organ was effective in each model, demonstrating SSI **organ specificity** in both cancer and infection
- In each infection model, the infection was caused by different species than the species from which the effective SSI is derived, indicating the therapeutic effect was due to **activation of innate immunity**, which confers **broad potential** application across many different bacterial and viral infections

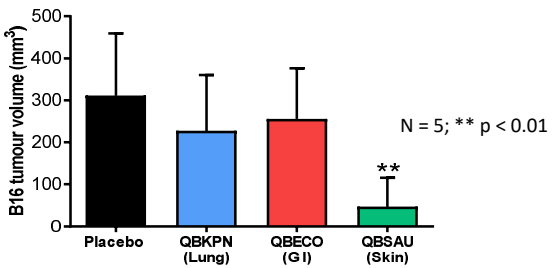
Lung Cancer Model



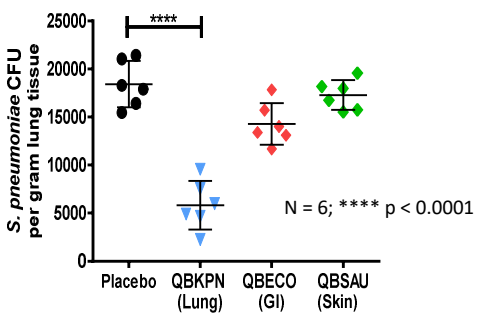
GI Cancer Model



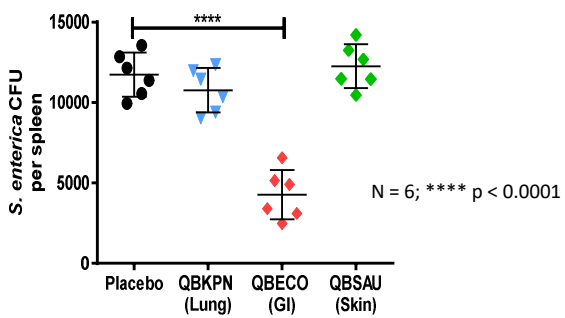
Skin Cancer Model



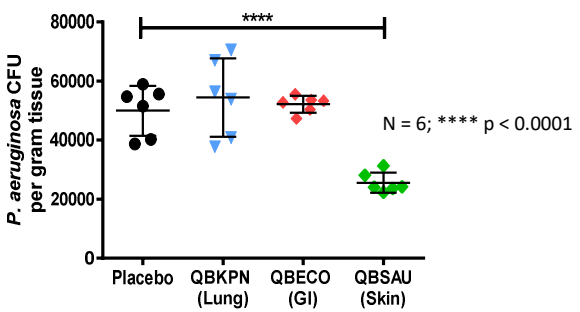
Lung infection (*Streptococcus pneumoniae* infection)



GI infection (*Salmonella enterica* infection)



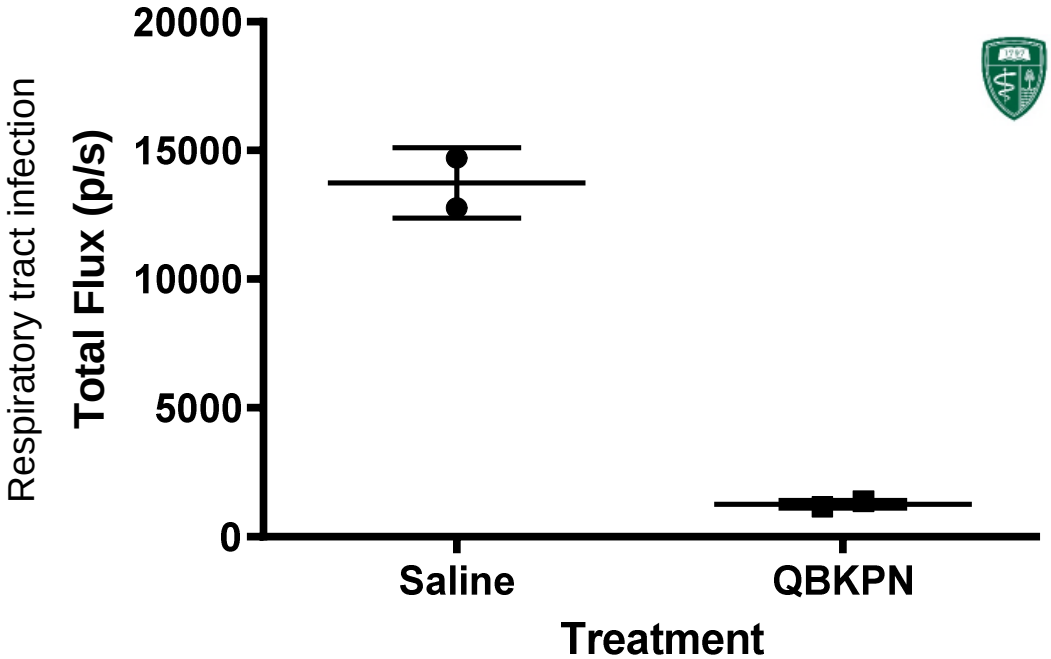
Skin Infection (*Pseudomonas aeruginosa* infection)



Qu's 3 organ-targeted SSIs and placebo were tested (s.c. administration) in mouse lung, GI and skin models of cancer (top) and infection (bottom)

This work is published in: Kalyan, S. *et al*. Distinct inactivated bacterial-based immune modulators vary in their therapeutic efficacies for treating disease based on the organ site of pathology. *Sci Rep.* **10**, 5901-z (2020).

QBKPN SSI: Substantially Reduces Viral Lung Infection



Dartmouth
GEISEL SCHOOL OF MEDICINE

n = 8 mice per group

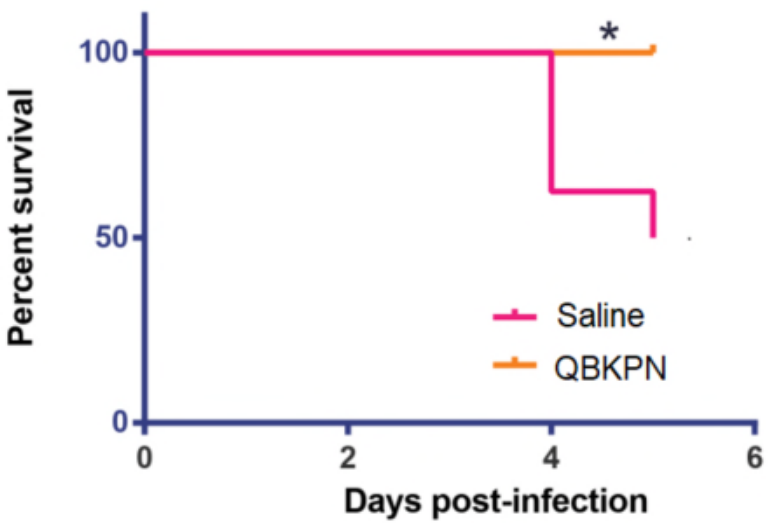
In collaboration with **Dartmouth College**, mice were prophylactically treated with either QBKPN (lung- directed SSI) or saline for 14 days prior to exposure to a virus (MHV68) known to infect the mouse respiratory tract. MHV68 virus expresses luciferase, which was used to assess the level of viral respiratory tract infection 3 days after exposure. As illustrated above, **QBKPN prophylaxis substantially limited viral lung infection**.

SSI Reduces Infection Morbidity/Mortality in Aged Mice

Prophylactic treatment of **aged** mice with QBKPN (lung-directed) SSI **substantially reduced** morbidity (as measured by weight loss) and mortality upon lung pathogen exposure

- Innate immune function **declines with age**, leaving the elderly at **high risk of infection** morbidity and mortality, as seen in the COVID-19 pandemic
- SSIs are designed to **restore** innate immunity to **prevent** morbidity and mortality from infection in the elderly

Survival of aged mice upon *S. pneumoniae* exposure



McMaster University

In collaboration with McMaster University, aged mice (18+ months, n=8) were prophylactically treated for 3 weeks prior to *S. pneumonia* challenge with either saline or QBKPN; significance in survival calculated with log-rank Mantel-Cox test, *p<0.03; significance in morbidity calculated with Tukey's multiple comparison test, **p<0.05

Qu biologics

Equity Funding and/or Licensing/Partnership Opportunity

Qu Biologics is seeking funding/collaboration/partnership to rapidly progress QBKPN and its transformational potential into Phase 2 (randomized controlled trial in COVID-19 high risk group) in this vitally important indication. Funding requirement through to end of Phase 2:

1. GMP production of QBKPN (USD$2M) for Phase 2 clinical trial
   - Drug substance, final drug product, and long-term stability
   - GMP cell bank already in place
2. Process development for commercial scale production (USD$500K)
3. Phase 2 randomized double-blind placebo-controlled trial to assess the efficacy of QBKPN SSI in preventing lung infection with COVID-19, influenza and other lung pathogens in elderly care home residents and other high-risk groups (USD$12M)
   - Randomized controlled trial (n = 300)

SSIs: Broad and Strong IP protection

- Qu has **strong and broad intellectual property** protection for its SSI platform with 74 patents granted and 49 applications pending
- Qu has been granted patents (2019) for the use of SSIs to prevent and treat viral and bacterial infections, including its application in viral pandemics, in the U.S. and Japan, with additional patents for this application anticipated in all the major markets
- Additionally, since SSIs are a novel biologics platform, it is expected that Qu's SSIs will receive a minimum of 12 years of **data exclusivity** in the US, 10 years in the EU, and 8 years in Japan

Qu Biologics Synopsis

- Clinical-stage private biotech company based in Vancouver, Canada
- Completed **three Phase 2** clinical studies
- 4th Phase 2 study underway, with 5th Phase 2 study to initiate Q2 2020
- More than **360 patients** treated with **very good safety profile**
- **Robust patent portfolio** with 74 patents issued and 49 applications pending across 5 patent families
- **Strong inspired team** ready to deliver on SSIs' transformative potential
- Animal study data at Dartmouth College suggests that Qu's SSIs could be used to prevent and treat a wide range of bacterial or viral infections

Meet The Team

Experienced and passionate team committed to deliver the promise of SSIs

MANAGEMENT TEAM

Hal Gunn, MD
Chief Executive Officer, BOD

- Founder of Qu Biologics
- Founder and past CEO of Inspire Health
- Inspired innovator and entrepreneur

Simon Sutcliffe, MD
Chief Medical Officer, BOD

- Past President and CEO of Ontario Cancer Institute, Princess Margaret Hospital and BC Cancer Agency
- President of International Cancer Control Congress Association

Alun Rees
VP, Manufacturing

- 30 years experience in cGMP manufacturing
- Past Director of Manufacturing at STEMCELL
- Past Director of Product Operations at QLT

Jim Pankovich, MSc, MBA
VP, Clinical Operations & Drug Development

- Over 20 years experience in drug development
- Past CSO of CIHR Canadian HIV Trials Network
- Past Senior Director at MIGENIX

Shirin Kalyan, PhD
Director, Scientific Innovation

- Adjunct Professor, Medicine, University of BC
- Translational innate immunologist
- Awarded Humboldt Fellowship (Germany)

BOARD OF DIRECTORS

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Hal Gunn, MD
CEO, BOD

Mike Leschuk, CA, CPA
BOD
Past-VP Finance, London Telecom

Yuchen Xia, MMath
BOD
Founder New Horizon Investment Management

Qu Biologics: Advisors, Collaborators and Partners

Clinical Advisory Team

Dr. William Sandborn
Dr. Brian Feagan
Dr. John Marshall
Dr. Brian Bressler

Scientific Advisory Board

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uOttawa
Dr. Adam Schuhendler

University of Victoria
Dr. Christoph Borchers
Dr. Dave Schibli

McMaster University
Dr. Jeremy Hirota

Qu Publications: References

Qu Biologics' peer-reviewed publications cited in this presentation are provided below:

1. Site Specificity MOA, preclinical data and broad potential therapeutic application:
   Kalyan, S. *et al*. Distinct inactivated bacterial-based immune modulators vary in their therapeutic efficacies for treating disease based on the organ site of pathology. *Sci Rep.* **10**, 5901-z (2020).

2. Phase 2 (n=68) randomized placebo-controlled trial in moderate-to-severe Crohn's Disease:
   Sutcliffe, S. *et al*. Novel Microbial-Based Immunotherapy Approach for Crohn's Disease. *Front. Med.* **6**, 170 (2019).

3. Preclinical data and clinical Phase 2 (n=11) trial data in moderate-to-severe ulcerative colitis:
   Sham, H. P. *et al*. Immune Stimulation Using a Gut Microbe-Based Immune Stimulation Using a Gut Microbe-Based Immunotherapy Reduces Disease Pathology and Improves Barrier Function in Ulcerative Colitis. *Front. Immunol.* **9** (2018).

4. Preclinical data and clinical Phase 2 (n=6) trial data in non-small cell lung cancer:
   Bazett, M. *et al*. Harnessing innate lung anti-cancer effector functions with a novel bacterial-derived immunotherapy. *Oncoimmunology* **7**, e1398875 (2017).

5. Preclinical data and clinical Compassionate use (n=12) data in moderate-to-severe Crohn's disease and ulcerative colitis:
   Bressler, B. *et al*. Site-Specific Immunomodulator: A Novel Treatment for Crohn's Disease. *Gastroenterol. Res. Pract.* **2015**, 231243 (2015).

6. Preclinical proof-of-concept data in asthma:
   Bazett, M. *et al*. A novel microbe-based treatment that attenuates the inflammatory profile in a mouse model of allergic airway disease. *Sci. Rep.* **6**, 35338 (2016).

7. Preclinical proof-of-concept data in COPD:
   Bazett, M. *et al*. Attenuating immune pathology using a microbial-based intervention in a mouse model of cigarette smoke-induced lung inflammation. *Respir. Res.* **18**, 92-y (2017).

Summary

INNOVATIVE APPROACH

"The **future of medicine** lies in treatments that restore our body's **innate capacity** to heal."

ROBUST DATA

BROADLY APPLICABLE PLATFORM TECHNOLOGY

STRONG IP

SIGNIFICANT MARKET OPPORTUNITY

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