# Senhwa Biosciences, Inc.

**6492 TW**

January, 2018

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# Agenda

- Executive Summary
- Product Strategy
- Key Success Factors
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# Executive Summary

- Founded in 2012, Senhwa Biosciences, Inc. focuses on the development of First-in-Class small molecule drugs used in targeted cancer treatments.
- Chairman Benny Hu and CEO Dr. Tai-Sen Soong formerly led CDIB Biosciences Venture Fund, one of the most successful biotech investment funds of its vintage.
- Lead products CX-4945 and CX-5461 with new mechanism of action (MOA) can be used as a single agent or in combination with marketed regimen to meet unmet medical needs.
- Senhwa owns the rights of 3 major class of compounds and holds 106 granted patents worldwide and 15 patents pending for approval.
- Internationally recognized and funded from prestigious institutions (i.e. Stand Up To Cancer, SU2C) and actively collaborating with the world's top scientists and medical research institutions to effectively manage risk and maximize clinical benefits to our patients.

# Chief Executives

## Benny Hu, Chairman

- MBA, the Wharton School at University of Pennsylvania
- Chairman & President, China Development Industrial Bank (CDIB)
- Founder & Chairman, CDIB Bioscience Venture Management (CBVM)
- Chairman and Director of Taipei 101, the tallest building in the world in 2004.

## Dr. Tai-Sen Soong, President & CEO

- Ph.D. of Biology, University of Illinois at Urbana-Champaign
- Founder, Vice Chairman & CEO, CDIB Bioscience Venture Management (CBVM)
- Managing Director, Imagen Venture Holdings
- Director of Development Center for Biotechnology (DCB), Taiwan
- Project Leader, Monsanto Company

# Management Team

**Polly S.C. Lin, Ph. D. – VP & Director, Clinical Dept., Taiwan Office**

- Ph.D., National Tsing Hua University, Taiwan
- In charge of preclinical research & clinical project management

**Sarah Chang, CPA – CFO & Head, Finance & Administration, Taiwan Office**

- VP of Operating group of Hua Nan SITC
- SVP of Underwriting Department at IBT Securities

**Chen-Fu Liu, Ph. D. - Director, R&D Dept., Taiwan Office**

- Ph.D., National Taiwan University
- R&D associate director of CVie Therapeutics.
- Member of a joint collaboration committee between CVie and ScinoPharm on identifying a new generation of heart failure treatment

**Maggie Lin, Supervisor, Internal Audit Office, Taiwan Office**

- Certified Internal Auditor (CIA).
- Auditor in Far Eastern Air Transport, then TWI Pharmaceuticals

**Hshiou-ting Liu, Ph. D., RAC - V.P. Chemistry and Pharmaceutical Operations, US Office**

- Ph.D., Boston College
- Oversees CMC (Chemistry, Manufacturing, and Controls)

**John Soong, M.D., FCAP – Chief Medical Officer, US Office**

- Fellow of the College of American Pathologists (FCAP)
- In charge of clinical design trial and new drug evaluation

**Lucas S. Chang, Ph. D.-V.P. General Counsel, US Office**

- Ph.D., Santa Clara University, School of Law
- Senior partner of Morgan, then Lewis & Bockius LLP

**Ruby Y. C. Wu, Manager, Administration and Finance, US Office**

- Baruch College, City University of New York.
- In charge of administration, finance and human resources in US office

# Advisors

## Daniel D. Von Hoff, M.D., FACP.

- Physician in Chief and Director of Translational Research at Translational Genomics Research Institute (TGen)
- Professor of Medicine, Mayo Clinic
- Chief Scientific Officer, VGPCC Clinical Trails Program at Scottsdale Healthcare

## Chan, Kwei-Hang (Keith) Ph.D.

- Senior advisor, Cornerstone Intellectual Property Foundation
- President & CEO, GloboAsia LLC
- Professor of NTU, NYMU and NCCU
- Led Asia innovative drug from research to approval

## Beverly M. Dixon

- MSQA, California State University – Dominguez Hills
- Founder, Quality Assurance Systems, LLC
- Over 2 decades of QA & regulatory experiences
- Senior QA Advisor, Pharma Resource Group

## Thomas Malefyt, Ph.D.

- Ph.D., University of California, Santa Barbara
- CEP, DesErrata LLC
- VP, CMC Operations, Syntex Research
- In-depth knowledge of strategic and tactical CMC plans and regulatory documentation review and preparation for US FDA

# Agenda

Executive Summary

**Product Strategy**

Key Success Factors

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# Product Platform

| Compound | Country | Indication | Preclinical | Phase I | Phase II | Phase III | Partner |
|---|---|---|---|---|---|---|---|
| CX-5461 | AUS | Haematologic Malignancies | | Ph I (Ph 1b) | | | PMCC |
| | CA | Breast Cancer | | Ph I/II | | | Dream team & CCTG |
| | | Ovarian Cancer (& other solid tumor) | | | Ph II | | |
| CX-4945 | USA, KR, TW | Cholangiocarcinoma (CCA) | | Ph I/II | | | |
| | USA | | | PK study | | | |
| | USA | Basal cell carcinoma (BCC); Medulloblastoma | | Ph I | | | |

# Product Overview

## Targeted Therapy

- CX-5461: targets G-quadruplex (G4); **G4 stabilizer**
- CX-4945: targets Casein Kinase 2 (CK2); **CK2 inhibitor**

## First-in-class small molecules

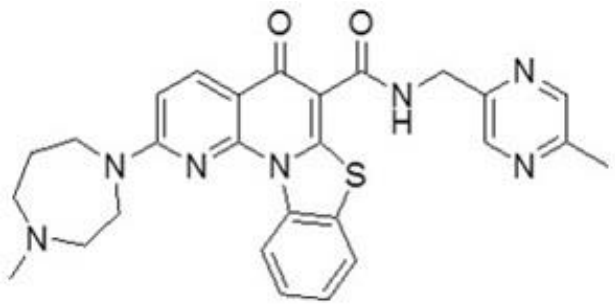
- Multiple indications focusing on unmet medical needs.
- **CX-5461**: Breast cancer, Hematologic cancer (Multiple Myeloma), Ovarian cancer and potential combination with immunotherapy.
- **CX-4945**: Cholangiocarcinoma, Basal Cell Carcinoma, Medulloblastoma and other potential indications.

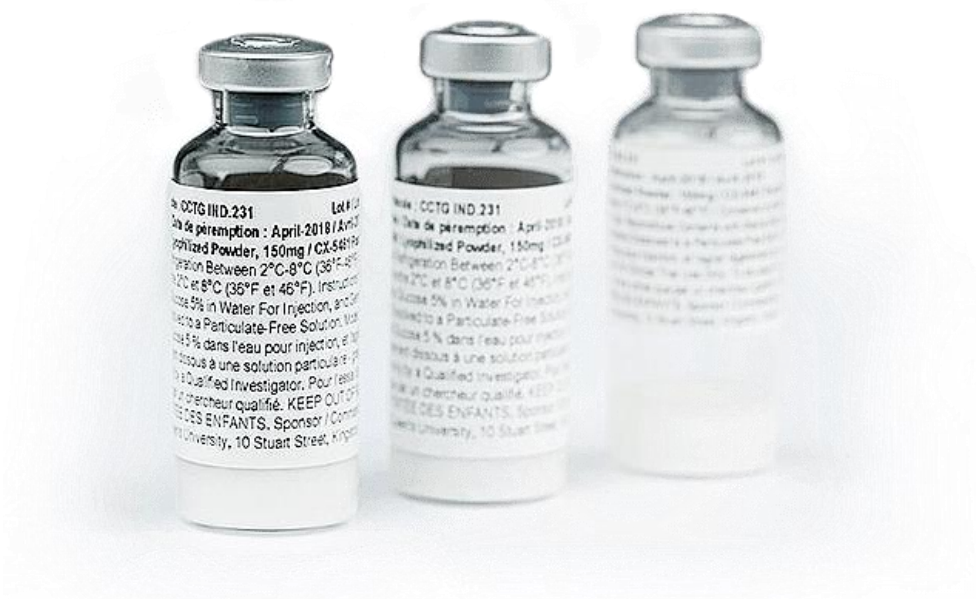
## Endorsement and recognition by renowned institutions

- Hematologic cancer trial is mainly supported by PMCC in Australia.
- Breast cancer trial is mainly funded by SU2C Canada-CBCF with a total grant of CAD$ 9M.

# CX-5461

**(First-in-class)**

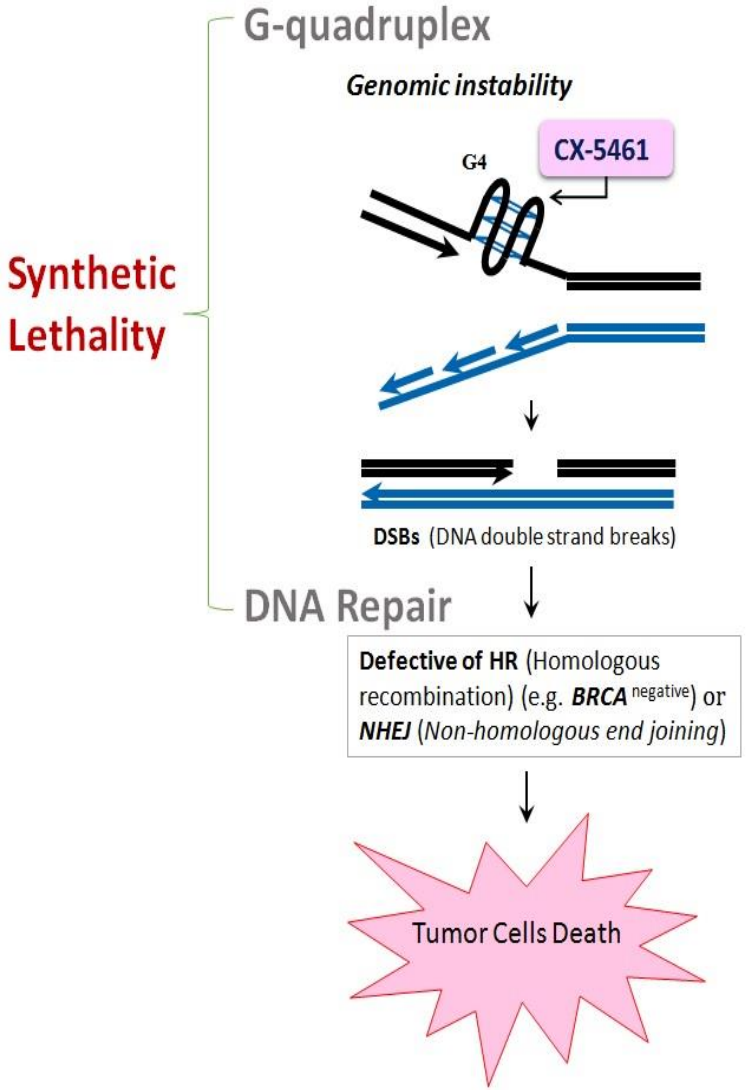


# CX-5461 Mechanism

Targeting G-quadruplex(G4) structure

- G-quadruplex (G4) stabilizer – causes DNA damage of tumor cells through a synthetic lethality approach in patients with BRCA1/2 mutations or HR deficiency (HRD).
- Clinical trials enroll patients with BRCA mutations and/or HR deficiency (HRD)



# CX-5461 Indications – TNBC

**Incidences:**

252,710 women in the US were diagnosed with breast cancer with ~20% TNBC

**Unmet medical need:**

Currently no targeted therapy. Treatment heavily relies on traditional chemotherapy. Patients with triple negative breast cancer have lower survival rate and higher relapse rate compared with other types of breast cancer.

**Potential new targeted treatment:**

PARP inhibitors: Lynparza (olaparib), Rubraca (rucaparib), Zejula (niraparib)

**CX-5461 rationale:**

Defects of enzymes involved in homologous recombination accounted for 15~25% of breast cancers. CX-5461 has different MOA comparing to PARP inhibitors , wider target genes in HR and longer duration of time to re-growth by treatment (PDX).

**Clinical Trial Status:**

- Breast cancer Phase I/II (Canada): Dose Escalation is continuing.
- CX-5461 is well tolerated in patients with generally mild to moderate adverse events noted to date
- PK analysis showed favorable and linear exposure with dose

# CX-5461 Indications – Ovarian Cancer

**Incidences:**

22,440 women in US are diagnosed with ovarian cancer each year.

**Unmet medical need:**

The first line treatment is commonly platinum-based regimen, but usually followed by early recurrence and platinum-resistant. Recurrent ovarian cancer is a lethal disease.

**New targeted treatment:**

PARP inhibitors: Lynparza (olaparib), Rubraca (rucaparib), Zejula (niraparib)

**CX-5461 rationale:**

Defects of enzymes involved in homologous recombination accounted for 50-70% of ovarian cancers. CX-5461 has different MOA compared to PARP inhibitors and with high safety.

**Clinical Trial Status:**

Wider target genes in HR and longer duration of time to re-growth in PDX model, potential to replace PARP inhibitors

We are currently in preparation for Phase II clinical trial planning to enroll PARPi- resistant patients.

# CX-5461 Indications – Multiple Myeloma

**Incidences:**

Over 30,000 patients in US diagnosed with multiple myeloma each year.

**Unmet medical need:**

Other than standard of care, Revlimid is used as a targeted therapy. Curative approach is still absent for multiple myeloma, particularly for refractory patients who are resistant to current treatments.

**Treatment:**

Chemotherapy and other drug (i.e. Revlimid), radiation, surgery, stem cell transplant

**CX-5461 rationale:**

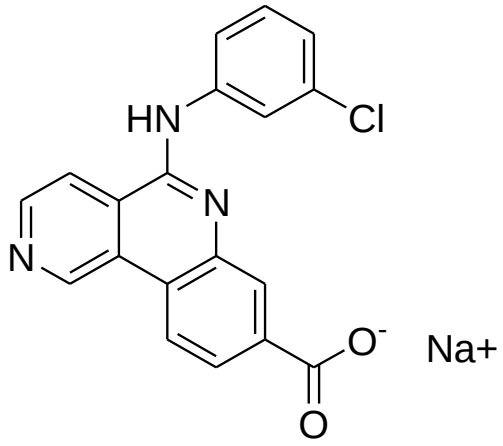
CX-5461 can drastically reduce the titer of M protein biomarker in patients resistant to Revlimid. As M protein is a key biomarker of of multiple myeloma.

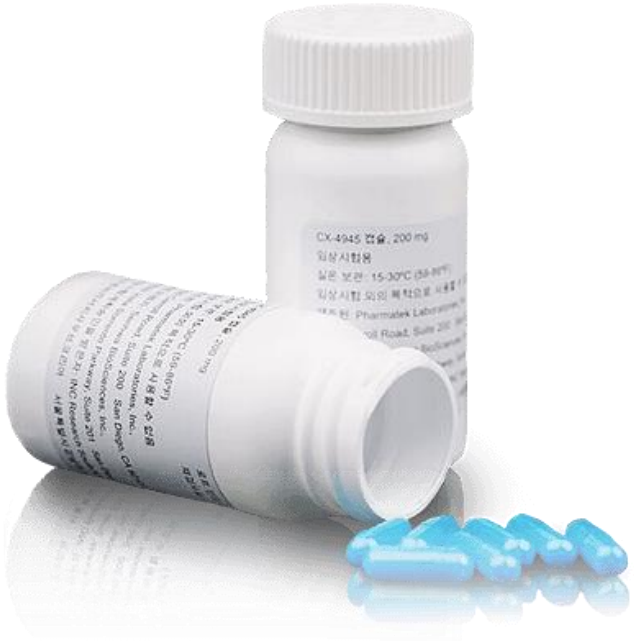
**Clinical Trial Status:**

- Phase I trial was conducted at PMCC and results showed 50% of patients with stable disease (3/6) in multiple myeloma patients.
- The clinical outcome led to adjust dosing level and frequency to maximize efficacy in the next stage of clinical trial.

# CX-4945

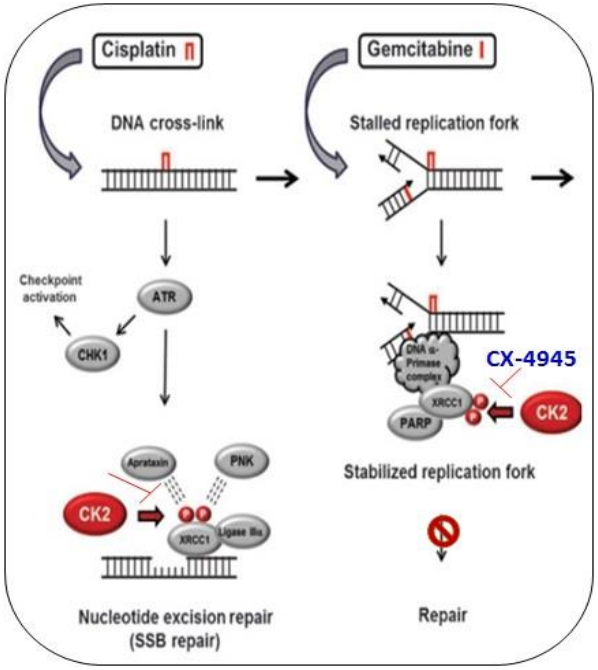
**(First-in-class)**



# CX-4945 Mechanism

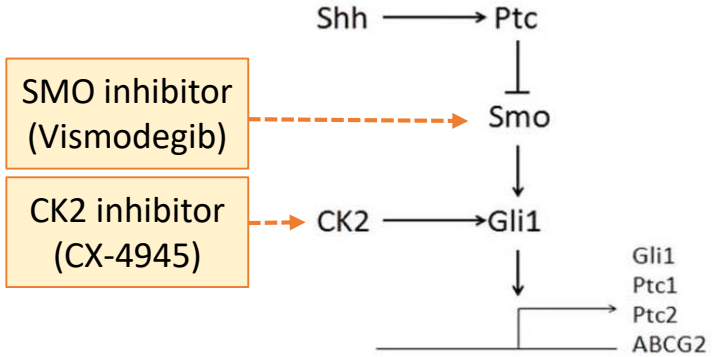
## Selective CK2 Inhibitor




Tumor DNA Repair Inhibition

- CK2 is a protein kinase that has elevated activities in many cancers.
- CX-4945 has been shown to inhibit the phosphorylation of the DNA repair protein XRCC1 and subsequently enhance the activity of DNA damaging chemotherapy agents

## Hedgehog pathway as a potential treatment target in BCC




Hedgehog (Hh) Pathway inactivation

- CK2 is a regulator of the Hedgehog (Hh) signal transduction
- CK2 is epistatic to SUFU and GLI.
- CK2 inhibition is an effective strategy against SMOi-resistant basal cell carcinoma.

# CX-4945 Indications - Cholangiocarcinoma

**Incidences:**

Approximately 8,000 new cases are diagnosed in US each year.

**Unmet medical need:**

Only 10 -40% of patients are eligible for surgery with 5-year survival rate of 25 -30%. Average 5-year survival rate is 5-10%. Chemotherapy is standard treatment for relapse or unresectable cancer.

**Standard chemotherapy regimen:**

Gemcitabine combined with cisplatin.

**CX-4945 rationale:**

In combination with Cisp/Gem, inhibits DNA damage repair, to delay resistance.

**Clinical Trial Status:**

- Currently being developed in combination with Cisp/Gem in cholangiocarcinoma (Phase I/II).
- CX-4945 has been shown to be safe, well-tolerated in both single agent study and current Phase I/II combination study.
- CX-4945 is well tolerated in 2 Phase I single agent studies (all-comers design) with 20% of patients extended duration on treatment and 14% experienced tumor reduction from baseline.

# CX-4945 Indications – Basal Cell Carcinoma

**Incidences:**

More than 4 million cases are diagnosed in US each year.

**Unmet medical need:**

Basal cell carcinoma which can't be surgically removed needs targeted therapy. However, resistance to SMO inhibitor occurs within 6 to 10 months after treatment. New targeted therapy is needed.

**Standard targeted therapy:**

SMO inhibitors: vismodegib (Ervedge) or sonidegib (Odomzo)

**CX-4945 rationale:**

CK2 is a potent regulator of the Hedgehog (Hh) signal transduction, targeting GLi1 rather than SMO. CX-4945 has the potential to become rescue medication for SMOi-resistant patients.

**Clinical Trial Status:**

Preclinical data suggested a potential use of CX-4945 for SMO resistant patients, and phase I trial plans to kick off in the first half of 2018.

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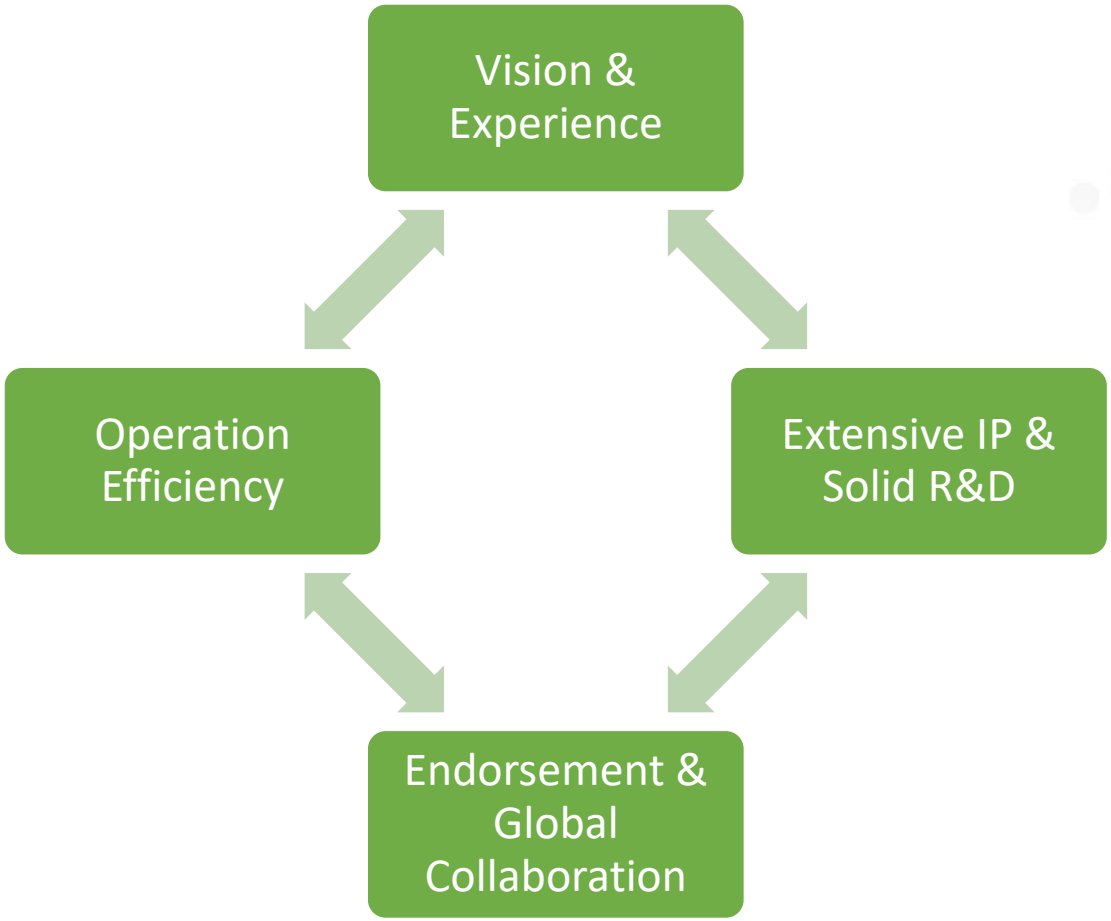
# Key Success Factors



# Precise vision to focus on potential blockbusters

- Dr. Soong acquired 30+ years of solid experience in pharmaceutical/ biotechnology investment. He has evaluated over 4,000 companies with an investment rate of only 1%.

- 79% of the invested companies obtained FDA approval for drugs, were listed publicly or acquired.

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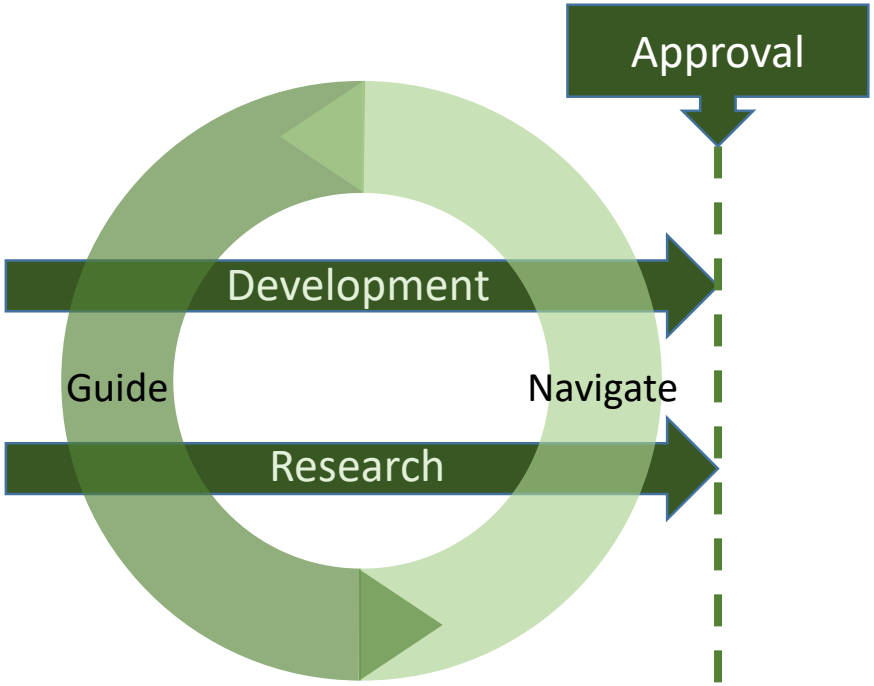
# Extensive IP Protection Backed by Solid R&D

- **<u>106 issued patents</u> & 15 pending approval (Jan, 2018)**
- Compound per se patent: CX-4945 (2027); CX-5461 (2028)
- Patent layout mainly in: United States, European Union, China, Japan, Canada, Australia, New Zealand, Russia, Israel, Hong Kong, Taiwan and South Korea


Patent Portfolio: Compounds, Method of Process, Medical Treatment, Crystalline, New Formulation and Combination Therapy

# Not Only Development - Research DOES Matters




- NRDO (No Research Development Only) is a popular drug development model.
- Senhwa is adapting NRDO model with a research twist:
  - The clinical data will guide the development direction, like a GPS navigation and will lead to the next step of research
  - The result from basic scientific research provides a reference to adjust the protocol of current clinical trial.

# Collaboration with 1st Tier Institutions

- Well-planned clinical trials and accurate execution with clear MOA enhances the success rate of innovative drug development.

| Product | Stage (Country) | Indication | Partner/Clinical sites |
|---|---|---|---|
| **CX-4945** | Phase I/II (US/KR/TW) | Cholangiocarcinoma | • Sponsor: Senhwa<br>• Clinical sites: **Mayo Clinic**; US Oncology; University of Colorado Hospital; Samsung Medical Center; Seoul National University Hospital; Severance Hospital; China Medical University Hospital |
| **CX-5461** | Phase I/II (CA) | Breast cancer | • Sponsor: NCIC Clinical Trials Group<br>• Clinical sites: British Columbia Cancer Agency (BCCA)-Vancouver Cancer Centre; Ottawa Hospital Research Institute; University Health Network |
| **CX-5461** | Phase I (AU) | Haematologic Malignancies | • Sponsor: **Peter MacCallum Cancer Centre** (PMCC)<br>• Clinical site: PMCC |

# Secure Funding Awards to Reduce Development Cost

- Reducing development risks is crucial for drug development companies. Senhwa's products are highly recognized by world-class renowned institutions and have been granted funding.

**Canadian Clinical Trial (NCIC)**

- SU2C Award
- CAD$ 9,000,000 (2015~2019)

CX-5461

**Australia Clinical Trial (PMCC)**

- NHMRC's Research Grant
- USD$ 839,271.5 (2012~2015)

CX-5461

More is on the way

CX-4945

CX-5461

# Stand Up to Cancer (SU2C)

- Founded in 2008, SU2C is a groundbreaking initiative created to accelerate cancer research that will expedite the development of new therapies quickly to save lives.
- 22 dream teams were selected to develop new treatments that have the potential to significantly affect patient care.
- Many breakthrough therapies have been accelerated and approved by FDA.

| | Dream Team | Drug | Sponsor | FDA Approved | Peak Sales ($B) |
|---|---|---|---|---|---|
| 1 | Breast Cancer Dream Team<br>Oct 2009 ~ Sep 2013 | Palbociclib<br>(Ibrance) | Pfizer | Feb 3, 2015 | $3-5.0 |
| 2 | Breast Cancer Dream Team<br>Oct 2009 ~ Sep 2013 | T-DM1<br>(Kadcyla) | Genentech | Feb 22, 2013 | $2-5.0 |
| 3 | SU2C-CRI Cancer Immunology Translational Dream Team<br>Mar 2013 ~ Feb 2016 | Pembrolizumab<br>(Keytruda) | Merck | Sep 4, 2014 | $7.0 |
| 4 | Pancreatic Cancer Dream Team<br>Dec 2009 ~ May 2015 | Abraxane +<br>Gemcitabine | Celgene | Sep 6, 2013 | $2.2 |

Source: *http://www.standup2cancer.org/impact*

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# 5-Year Balance Sheet

| NT$ Million | 2012 | 2013 | 2014 | 2015 | 2016 | 3Q17 |
|---|---|---|---|---|---|---|
| **TOTAL ASSETS** | **400** | **827** | **918** | **746** | **532** | **1,690** |
| Cash | 400 | 754 | 839 | 734 | 514 | 1,656 |
| NR&AR | 0.1 | 1.8 | 3.0 | 2.9 | 1.5 | 1.6 |
| Inventory | 0 | 0 | 0 | 0 | 0 | 0 |
| Fixed Asset | 0 | 0 | 1.9 | 1.5 | 1.9 | 6.4 |
| **TOTAL LIABILITIES** | **0.4** | **14.5** | **13.6** | **15.6** | **20.8** | **12.2** |
| Bank Loans | 0 | 0 | 0 | 0 | 0 | 0 |
| NP & AP | 0.4 | 11.4 | 13.3 | 12.8 | 20.7 | 12.0 |
| **TOTAL EQUITY** | **399** | **812** | **904** | **731** | **512** | **1,678** |

| YoY(%) | | | | | |
|---|---|---|---|---|---|
| 2012 | 2013 | 2014 | 2015 | 2016 | 3Q17 |
| **NA** | **106.8** | **11.0** | **(18.7)** | **(28.7)** | **195.5** |
| NA | 88.8 | 11.2 | (12.6) | (29.9) | 199.6 |
| NA | 1,205.8 | 63.0 | (2.6) | (49.7) | 32.4 |
| NA | NA | NA | NA | NA | NA |
| NA | NA | NA | (24.4) | 32.5 | 203.2 |
| **NA** | **3,585.8** | **(6.5)** | **14.7** | **33.6** | **71.0** |
| NA | NA | NA | NA | NA | NA |
| NA | 2,848.4 | 16.9 | (4.2) | 62.1 | 73.1 |
| **NA** | **103.3** | **11.3** | **(19.2)** | **(30.0)** | **197.1** |

# 5-Year Income Statement

| NT$ Million | 2012 | 2013 | 2014 | 2015 | 2016 | 3Q17 | YoY(%) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | 2012 | 2013 | 2014 | 2015 | 2016 | 3Q17 |
| Sales Revenue | - | 26 | 24 | - | 0.1 | - | NA | NA | (10.0) | (100.0) | NA | NA |
| Gross Profit | - | (3) | 0.17 | - | 0.1 | - | NA | NA | (106.7) | (100.0) | NA | NA |
| Operating Profit | (0.9) | (116) | (163) | (201) | (258) | (261) | NA | 974.3 | 40.3 | 23.2 | 28.4 | 44.8 |
| Income before Tax | (0.7) | (113) | (156) | (191) | (254) | (257) | NA | 1309.8 | 37.5 | 22.8 | 33.1 | 43.3 |
| Net Income to Parent | (0.7) | (113) | (156) | (194) | (255) | (257) | NA | 1309.8 | 37.5 | 24.7 | 31.4 | 43.7 |
| EPS(NT$) | (0.02) | (2.57) | (2.48) | (2.96) | (3.89) | (3.63) | NA | 1185.0 | (4.7) | 20.8 | 31.4 | 26.7 |

Senhwa
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