股票代號:1720



### Standard Chem. & Pharm. Co., Ltd. (SCP)

### **Investor Conference**

2019.11.21





# 免責聲明 Safe Harbor Notice

本次簡報與討論包含特定預測性的說明,而其內容有關於營運結果、財務狀況,以及對未來事件的預期。因為此等前瞻性說明是有關於未來事件,而且取決於未來發生時的環境因素,所以必然含有風險與不確定性。

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In these presentations and discussions, there are certain forward looking statements regarding the results of operation, financial condition and current expectation about future events. As forward-looking statements relate to events and depend on circumstances in the future, they involve risk and uncertainty.

We do not undertake any obligation to publicly revise or update any forward looking statements for availability of new information, future events or otherwise. Real result probably differ substantially from those expected in these forward-looking statements.



### Agenda









### Introduction to Standard Pharmaceutical Group (SCP Group)

# **SCP's International Honors**







F



**2000** SCP is the first TW pharmaceutical company to pass US FDA inspection

1998 SCP is the first Taiwanese pharmaceutical company to be ISO9001 certified

SCP continuously passed US FDA follow-up inspections with no 483s





**2008** SCP received PMDA's "Certificate of Foreign Drug Manufacturer"

**2018** FDF Plant and API Plant passed PMDA inspection



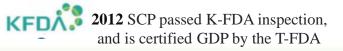




2009 SCP's API plant passed TGA inspection



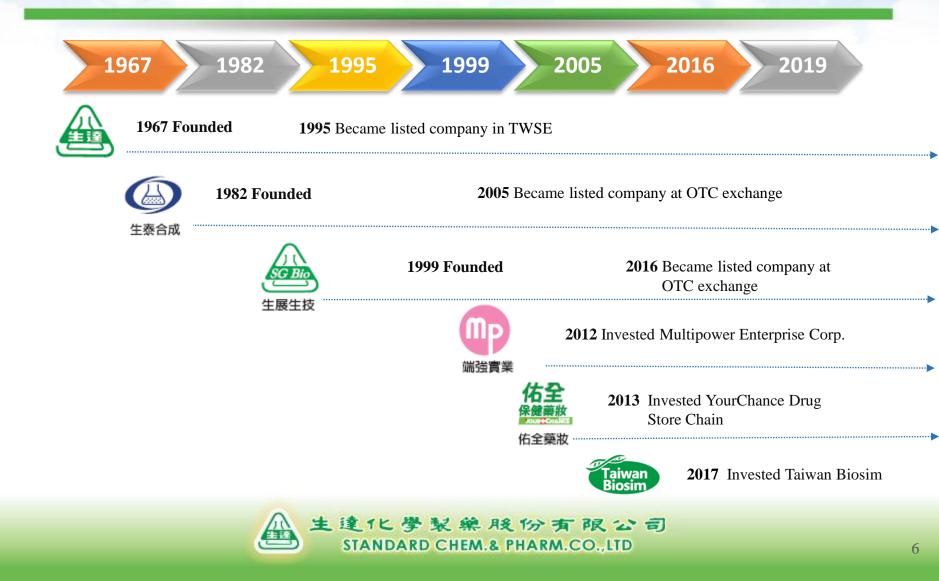
**2010** SCP passed TW PIC/S GMP inspection **2012** SCP passed TFDA GDP inspection





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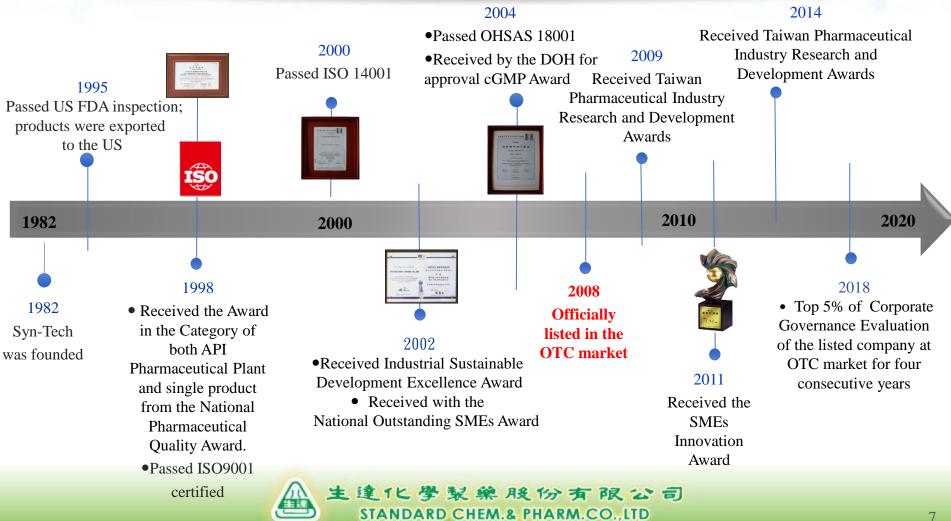
### Associated and Related Company of SCP STANDARD







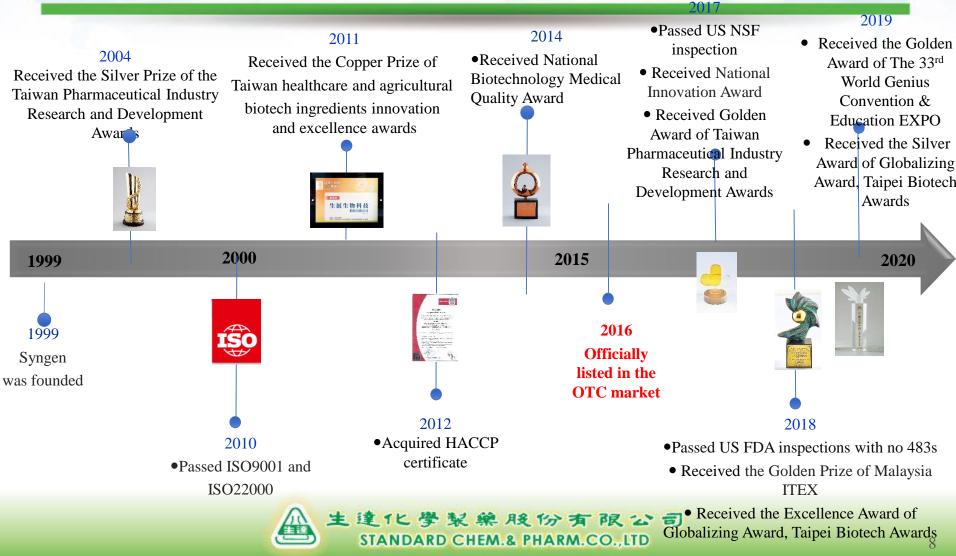
### Syn-Tech Chem. & Pharm. Co., Ltd History







# Syngen Biotech. Co., Ltd History

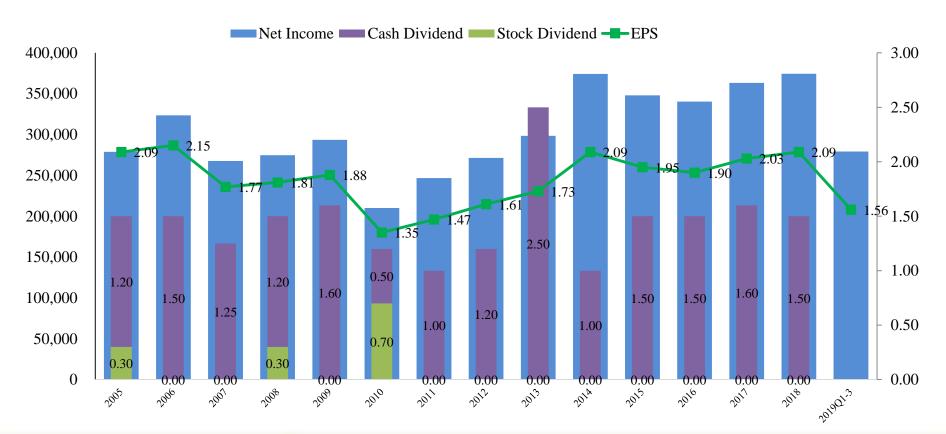




# **52 Years of Continuously Profitable** (15 years of Profit and Dividend Performance)

Income after Taxes

(Expressed in thousands of New Taiwan Dollars)





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10

**EPS** 



# 2019 Financial Results through Q3

12.1

12.3

.0

29.1

2.6

10.3

21.0

2.6

28.7

8.2

20.6

24.6

0.6

24.0

19.2

7.6

20

### **Income Statement** (Consolidated)



(Expressed in thousands of New Taiwan Dollars)

	2019 (Q1~Q3)		2018 (Q1~Q3)		(±)	Growth Rate
	Amount	%	Amount	%	Amount	%
Operating revenue	2,905,898	100	2,574,307	100	331,591	13
Operating cost	1,653,061	57	1,452,919	57	200,142	14
Gross profit	1,252,837	43	1,121,388	43	131,449	12
Operating expense	899,565	31	846,160	33	53,405	6
Operating profit	353,272	12	275,228	10	78,044	28
Non-operating income and expense	89,147	3	98,783	4	-9,636	-10
Income before tax	442,419	15	374,011	14	68,408	18
Net Income	349,651	12	312,664	12	36,987	12
Net income attributed to Stockholders of the Parent Company	279,115	10	279,844	11	-729	0
EPS(NT\$)	1.56		1.57		-0.01	-1



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### **Balance Sheet** (Consolidated)

(Expressed in thousands of New Taiwan Dollars)

	2019/9/30		2018/9/30	
	Amount	%	Amount	%
Cash and cash equivalents	1,402,403	21	893,312	14
Accounts receivable	951,913	14	948,891	15
Inventories	907,278	13	831,266	13
Investments	560,860	8	616,374	10
Property, plant, and equipment	2,114,539	31	2,147,236	34
Other current and non-current assets	924,792	13	902,856	14
Total Assets	6,861,785	100	6,339,935	100
Current Liabilities	2,023,565	29	1,647,545	26
Long-term loans	84,691	1	189,799	3
Other liabilities	458,960	7	323,617	5
Total liabilities	2,567,216	37	2,160,961	34
Total shareholder's equity	4,294,569	63	4,178,974	66
Total liabilities and shareholder's equity	6,861,785	100	6,339,935	100



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#### **Global Revenue Ratio of past 5 Years** STANDARD (Consolidated)

(Expressed in thousands of New Taiwan Dollars)

Export Sales

9.2%

80.8%

2018

16.9%

83.1%

2019(Q1~Q3)

Ratio of International-to-Domestic

Sales of past 5 years

19 49

80.6%

2017

Domestic Sales

17.5%

82.5%

2016

13.4%

86.6%

2015

100%

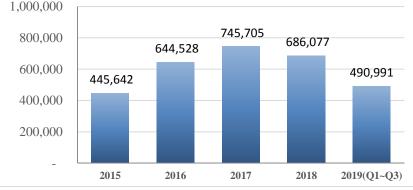
80%

60%

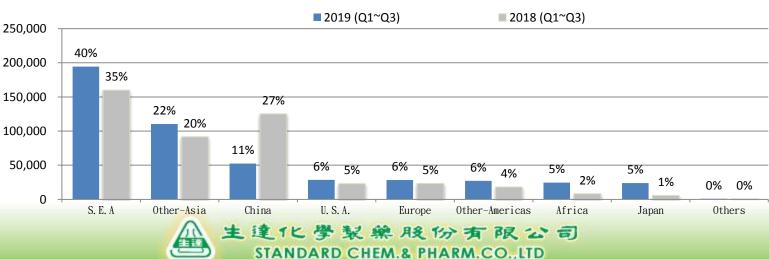
40%

20% 0%

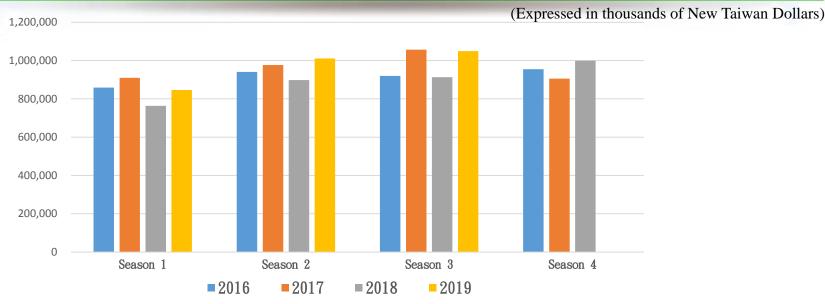
#### International Sales of past 5 years



International Revenue (Ex-Taiwan)



### Comparison of Quarterly Revenue of past 4 years (Consolidated)



Consolidated Revenue	Season 1	Season 2	Season 3	Season 4	Annual Statistics
2016	859, 024	940, 238	919, 663	954, 876	3, 673, 801
2017	909, 933	976, 177	1,056,753	905, 821	3, 848, 684
2018	763, 261	897, 693	913, 353	998, 786	3, 573, 093
2019	846, 175	1, 010, 837	1, 048, 886		



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# **Forward-looking Strategy**



### **Future** Milestone



### **Taiwan Generics**

### International Better than Generics



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### **SCP – Major International Operations of the past 2 years**

#### Taiwan

- Agent for brand drugs
- Exclusive agent for 20
  Mylan anticancer drugs
- Continuously developed high technical threshold generic drugs

#### China

- Continuously commercialized opportunities through Generic Quality Consistency
  - Evaluation(GQCE)
- Applied for approval of own products

#### Japan

- Continuously exported
  Bronchiolitis medication
- Anti-inflammatory Oral
  Solid Dosage started to
  ship out in 2019 ;
  schedule to launch in 2020





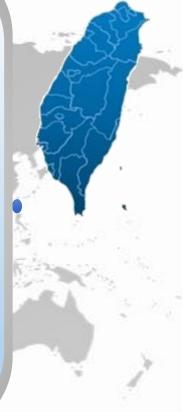
### **Revenue Growth Strategy - Taiwan**

#### Taiwan as Base of Operations for Global R&D and Pharmaceutical Manufacturing

- Yearly increase of international operations ratio.
- Support the technologies and products required by the international market (US, China, Japan, ASEAN)

#### Strengthen Manufacturing Capability

- Manufacturing line complies with international standards; have passed numerous international audits
- Production line simplification
- Continuing production expansion and upgrade equipment
- Distribution :
  - Distribute Japanese brand psychiatric drug aiming at more than NT\$100 million revenue in 2020.
  - Distribute 20 Mylan anticancer drugs in Taiwan





# **Distribution of 20 Mylan anticancer drugs in Taiwan**



- Biopharmaceutical Biosimilar
- 3 ingredients, 5 drug licenses
- 3 drug licenses have been approved in Taiwan
- 1 drug was officially approved with NHIA reimbursement price

### 15 kinds of Small Molecule Drugs

- 9 ingredients, 15 drug licenses
- 12 drug licenses have been approved in Taiwan
- 11 drug was officially approved with NHIA reimbursement price





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# Mylan Ogivri

#### Herceptin

- The product is ranked 4<sup>th</sup> in global drug sales, and it has taken the first spot of cancer NHIA expenditures for many years.
- The product was approved with NHIA reimbursement price in 2002, and the current NHIA reimbursement Price: NT\$46,895/dose; 2018 annual NHIA expenditure was NT\$2.206 billion with 5,030 applicants.

#### Mylan Ogivri

- The product was approved and launched in the U.S. in December 2017, and also approved in Taiwan in December 2018; it's expected to ship out in December 2019.
- NHIA reimbursement Price: NT\$ 39,860/dose, one dose usage for every 3 weeks, around 18 doses each year
- Indication: EBC \ MBC \ MGC
- Breast Cancer Patients
  - Breast cancer takes the first place of Taiwanese female cancer, with the fourth spot of leading cause of death
  - Breast cancer patients are increased 12,000 every year in Taiwan 主道化学教察报份有限公司 STANDARD CHEM.& PHARM.CO.,LID



# **Revenue Growth Strategy - China**



#### **SCP Competitiveness**

- SCP has successful experience with U.S. and Japan regulatory dossiers
- SCP to continue to specialize expertise in BE design and execution

#### **Mid-Term Goals**

- Increase technology in-flow
- Increase revenue from profitsharing

#### **Collaboration Model**

- Tech-transfer
- Co-development
- BE Collaboration
- Profit-sharing Partnerships



#### **Drug Licenses Review**

- Continuously ship antibiotic injection products
- Expect to launch diabetes products in 2021

### **NMPA GQCE**

- 2017: 2 contracts signed
- 2018: 5 contracts signed
- 2019: expected to sign 1 contract
- 2020: aiming to sign 6 contracts

#### **Results**

- Increase the number of cooperative projects and cooperative pharmaceutical companies
- Diversified corporation structure



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# NMPA Reforms: GQCE [Revised]

### **Cost of Research and Development**

• According to Pharmcube's statistic, for listed companies, there are 77 items passed Generic Quality Consistency Evaluation, and 11 of the passed items cost more than NT\$ 10,000,000 in research and development.

### Revised status of GQCE

	Revised Docs with No.	Items	Entities
Total in 2018.12(PS.1)	676	231	249
Total in 2019.03(PS.2)	1,102	336	361
Total in 2019.11(PS.2)	1,695	456	476

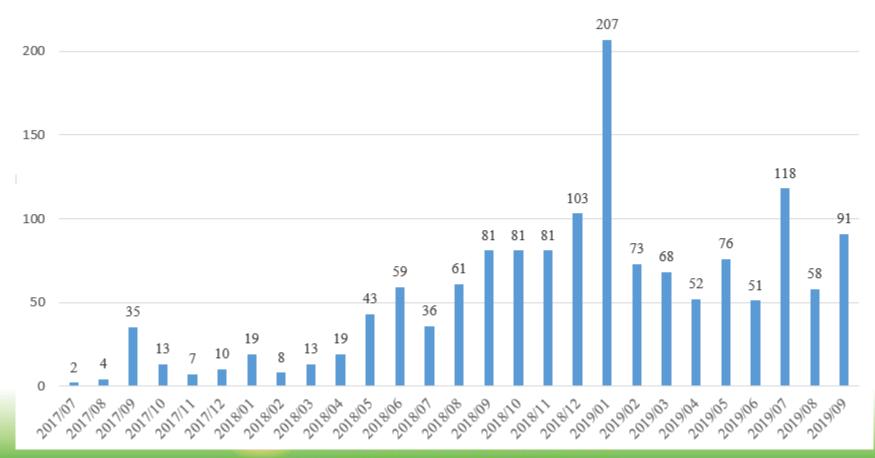
PS.1: 2018.12.29 www.yaozh.com Report of CDE Statistics

PS.2:2019.04.02,2019.11.04信狐德部学家樂段份有限公司 STANDARD CHEM.& PHARM.CO.,LID



### NMPA Reforms: GQCE [Submissions]

• The submission is still heat up, 2017.07~2019.09 Consistency Evaluation: 1,469 submissions were revised in total





### **NMPA Reforms: Total revised & approved submissions**

2017.07~2019.09 1,469 submissions were revised in total, 360 submissions were passed





# NMPA Reforms: GQCE [Passed]

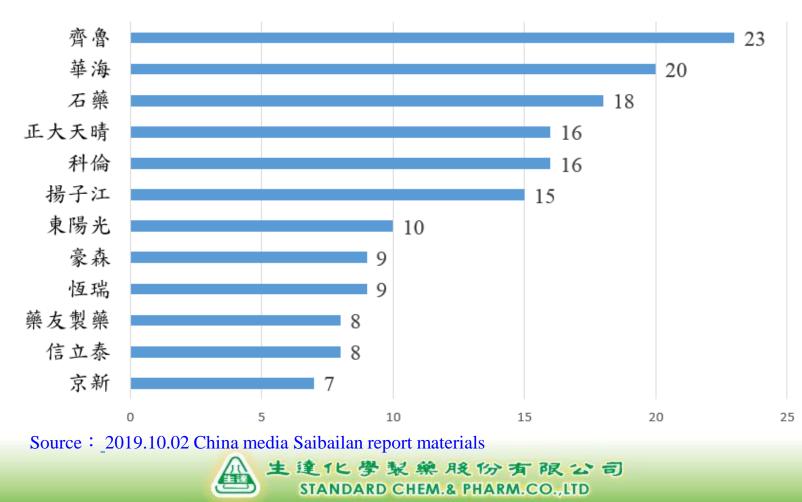
- Up to October 2<sup>nd</sup>, 2019, 32 ingredients have more than 3 approved sources.
- 143 pharmaceutical companies totally have 345 items (including 202 ingredients) which has passed GQCE.

No.	Items	passed GQCE companies
1	Amlodipine Besylate Tablets 5mg	11
2	Montmorillonite Powder 3g	10
3	Tenofovir Disoproxil Fumarate Tablets 0.3g	9
4	Metformin Hydrochloride Sustained-Release Tablets 0.5g	9
5	Cefuroxime Axetil Tablets 0.25g	7
6	Metformin Hydrochloride Tablets 0.25g	7
7	Rosuvastatin Calcium Tablets 10mg	6
8	Levocetirizine Hydrochloride Tablets 5mg	6
9	Rosuvastatin Calcium Tablets 5mg	5
10-21	12 Pharmaceutical Ingredients	4
22-32	11 Pharmaceutical Ingredients	3

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Source: 2019.10.02 China media Saibailan report materials

### The ranking of Top 10 Pharmaceutical Companies which passed GQCE



過評產品數Top 10 藥企(含子公司)

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# **Revenue Growth Strategy - Japan**



#### **Collaboration Model**

- Japanese Distribution Partner
- Contract Development, SCP Manufacturing
- License Holder



#### **Raw Material Strategy**

- Collaborate with Syn-Tech Chem. & Pharm. Co., Ltd.
- API Vertical Integration

#### **Current State**

 Obtained marketing license for Montelukast (Asthma), 3<sup>rd</sup> straight year of continuous export



#### **Under Development**

- Co-development of Nonsteroidal Antiinflammatory Drug (NSAID) – passed BE in 2018
- Start exporting in 2019; expect to receive license in the first quarter of 2020.



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### **Revenue Growth Strategy – U.S.A.**

#### Strategy

**U.S.A. Market** 

- Collaboration with Syn-tech Chem. & Pharm. Co. Ltd.
- API Vertical Integration via strategic partnerships

#### U.S.A. Market

- Largest Rx Market
- Characterized by lengthy review timelines.
- Expensive compilation and filing costs
- Part of SCP's long term goals

#### **Current State**

- Actively export one diabetic treatment
- One approval, pending patent settlement terms
- Two ANDA's under review





### **Forward-looking Strategy Layout**



Increase International Revenue Ratio

- Increase international business resources
- Recruit international talent

Specialized technology and professional development of international performance

> • Develop Taiwan into a base of cutting-edge R&D technology and revenue generation.

Leverage Competitiveness in Overseas Markets

- Stable foundation
- Rapid revenue creation
- Step-by-step optimization for minimization of loss
- Focus on market knowledge and business acumen
- Establish strategic partnerships for mid- and



生達1と学製樂股份有限公司long-term goals STANDARD CHEM.& PHARM.CO.,LTD



# **Corporate Social Responsibility**



### **Fan Dao Nan Foundation**



#### **Fan Dao Nan Foundation**

- •Established in 1987
- •Endowment Fund: NT\$196 Million
- •Annual Budget: NT\$12 Million

#### **Principal Activities**

- Cultural and educational
  - development activities
- Scholarships and Talent Cultivation Sponsor R&D and Innovation





#### **Rewards and Honors Received**

• Non-profit education

- 2011: Special Recognition Award Dept. of Education
- 2012: Tainan City Govt. Grant for Scholarship Program
- 2013: National Special Selection Award for After-School Program – Dept. of Education





# **Corporate Social Responsibility**

#### Scholarships

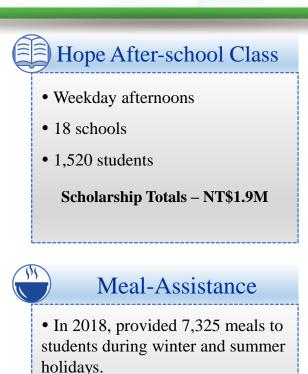
- University (related fields): 2 universities/5 students
- High school: 8 schools/113 students
- Middle school: 56 schools/814 students
- Elementary school: 232 schools/2,681 students

 $Scholarship\ Totals-NT\$6M$ 

#### Other Sponsorships

• Member of 19-corporation alliance for sponsorship cultural and educational advancement

#### **Grant Total – NT\$500K**



**Assistance Totals – NT\$440K** 

FamilyMart



#### Sunflower Wednesdays

- Every Wednesday afternoon
- 4 schools
- 310 students

 $Scholarship\ Totals - NT\$250K$ 



#### Charity

- .
- SCP Children's Drawing Competition
- SCP National Table Tennis Competition

#### Prize Totals - NT\$1.65M



520



### **Public Service Activity: Bone Mass Measurement**





- Cooperate with medical institution, local community, and pharmacy for conducting public service activity: bone mass measurement.
- The bone mass measurement activity were hold 29 times in 2019; 2,600 people in total were measured

# The First Senior Gym in Taiwan – The Center of Athletic Training and Health







- Location: Chiayi Yangming Hospital (No. 383, Minquan Road, West District)
- Intelligentized analysis of test result; customized design for sports course
- Provide a comfortable and professional health promotion place for middle-aged and senior people
- From July 2019 to the end of October, the total user count is about 1,400.









# **Thanks for your attention**

