

The **First,**
Best &
Most

Microneedle Technology
Beyond Imagination

혁신적 약물 전달체계
(용해성 마이크로니들 기술 소개)



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Painful Injection

**Needle phobia:
More than 5% of people**



Cold Chain Supply



COVID-19 VACCINE PROGRESS IN THE WORLD'S MOST POPULOUS NATIONS



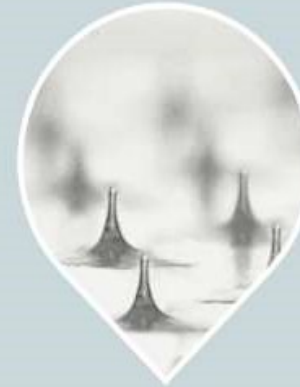
Source: CNN Health - Global Vaccination Data

패치의 간편함과 주사의 효율적인 약물 전달의 장점을 결합한 “**패치형 무통증주사**”라고도 합니다.

미세한 바늘로 피부를 통해서 약물을 전달하는 방법 마이크로니들은 기존 주사기(hypodermic needle)의 단점인 통증, 외상, 감염, 거부감 등을 극복한 새로운 차원의 약물전달 시스템으로써 환자의 거부감을 없애고 고효율로 약물을 전달할 수 있는 ‘**경피 약물전달 기반기술**’입니다.



고형화 제제



고분자 물질
전달 가능



상온 보관 및
유통 편리



용해성
마이크로니들의
장점

사용의 편리성

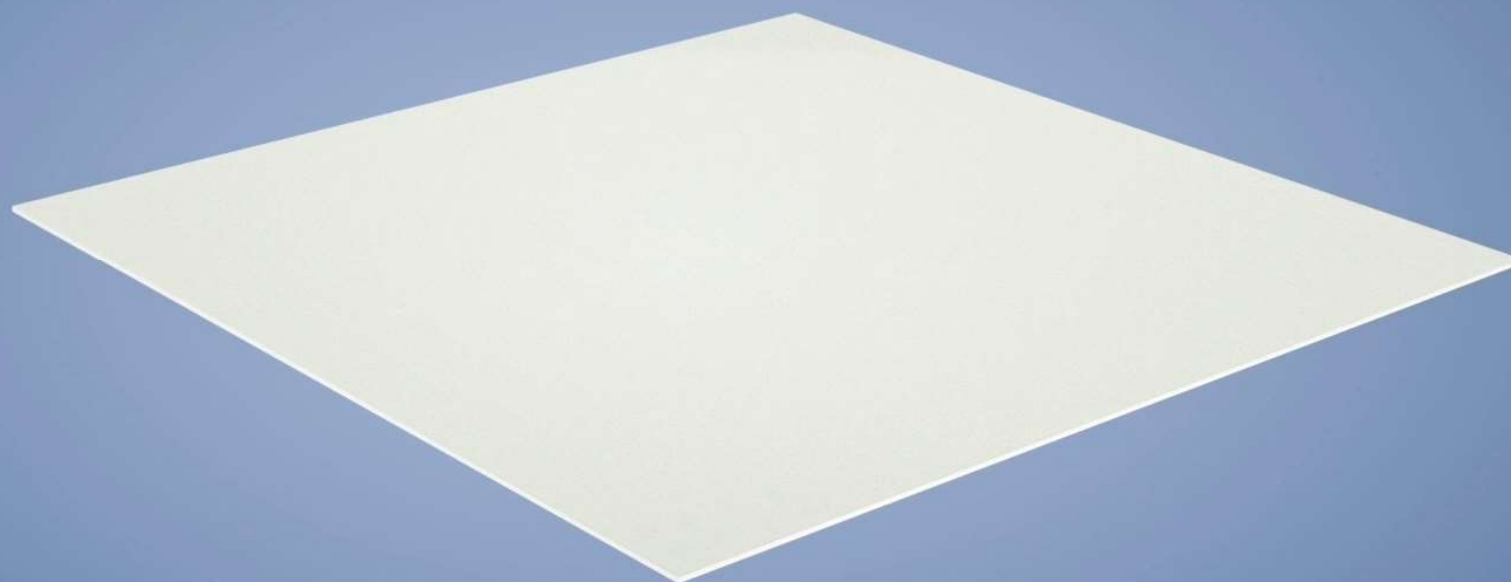
- 패치 제제로 소지가 편리
- 물 없이 사용 가능
- 식이와 관련 없이 사용 가능
- 치매 환자 투약 편리

낮은 부작용

- 경구 복용에 따른 소화위장관계 부작용 감소
- 주사에 따른 2차 감염 감소

무통증 제제

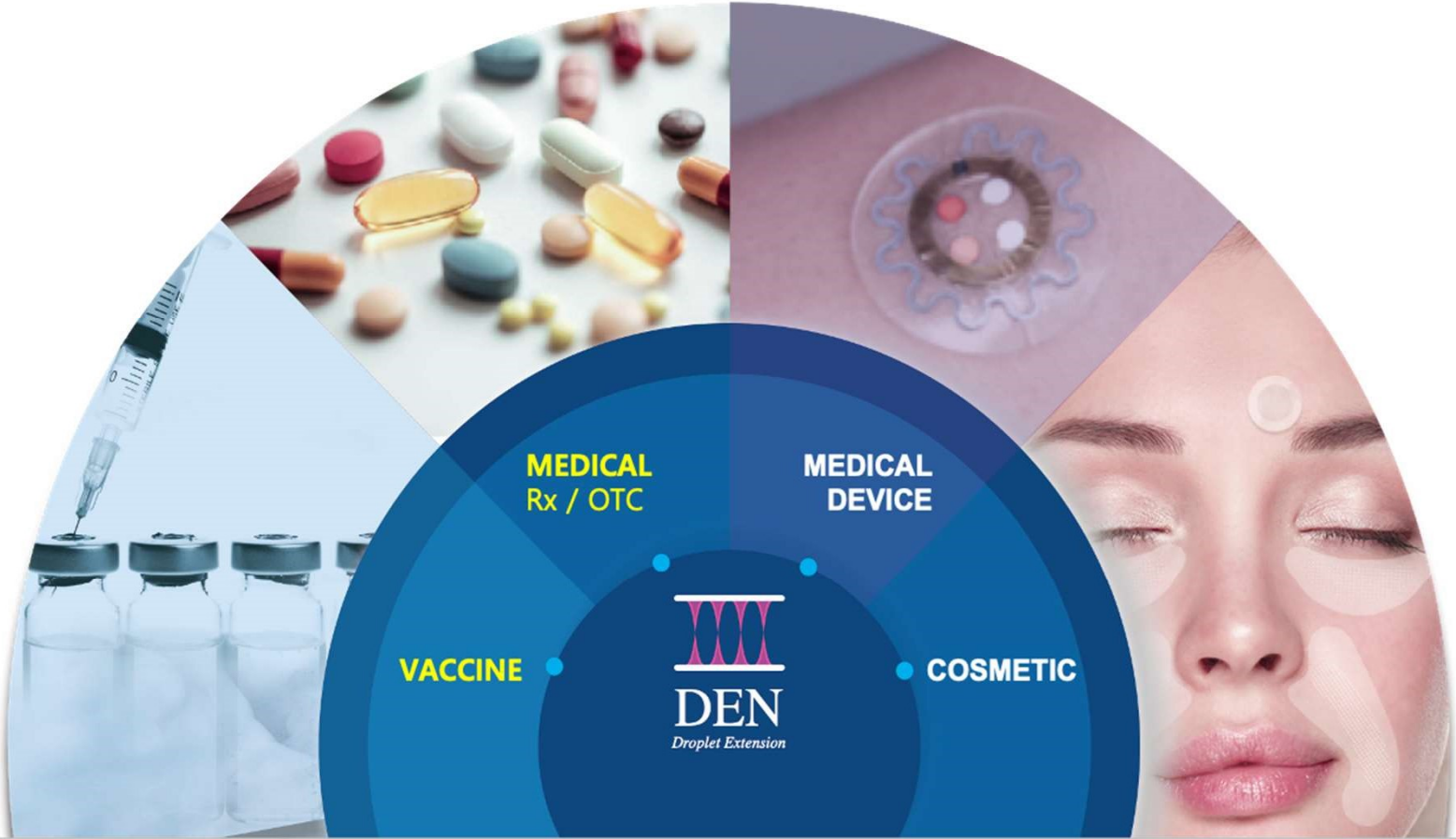
- 마이크로니들은 무통증 제제
- Needle phobia 사용 가능
- 어린이/노약자에게 사용 편리



DEN
MICROCONE® PATCH

DEN Microarray technology has potentiality for total human health care.

Patch derma cosmetic, Medical device, Medicine & Vaccine patch



Innovative Microarray Drug Delivery System

THE PATH TO HEALING

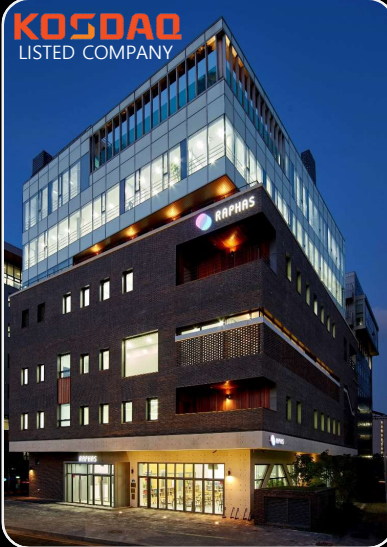
Raphas is a pioneering world-class technology company that is paving the way towards healing and human health.

Established in
2006

Personnel
90

DEN
Technology
& 76 Patents

Capable of
Commercial
Manufacturing



◀ Raphas HQs & Investigational GMP

- ▼ 1st Commercial GMP Factory in Korea
- Cosmetic GMP (5 lines)
 - OTC Pharmaceutical GMP (1 line)



▲ 2nd Commercial GMP Factory in Japan

- ISO22716 / Cosmetic GMP
- ISO13485
- Clinical GMP / pharmaceutical cGMP



▲ Vaccine Patch Joint Company in USA



THE PATH TO HEALING

Raphas is a pioneering world-class technology company that is paving the way towards healing and human health.

**HQs,
Investigational Medical product
GMP Facility in Seoul**

System

1st Commercial GMP Factory in Cheonan, Korea

- High Functional Derma-cosmetics
- OTC medical products



2nd Commercial GMP Factory in Shizuoka, Japan



Vaccine Joint R&D Company



Automatic In-line Manufacturing System



Vaccine & Therapeutic DEN MAP Pipeline

Dermatological OTC Drug



Killa acne ES

Salicylic acid

ZITSTICKA

- 2022. USA 공급 계약
- 2023. 04. 미국 출시
- 2023. 06. 미국 FDA OTC 제조시설 실사 완료



흉터 치료제

Allantoin/Dexpantenol

In-house

- 제형연구

Prescription Drug



RapMed-1506
면역 치료제

House dust mite ext.



- 2015 세브란스 연구중심병원과제 시작
- 2022년 환자 대상 임상 1상 시작



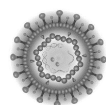
RapMed-2003
당뇨/비만 치료제

Synthetic Semaglutide



- 대원제약 공동개발
- 2020-2024 바이오산업핵심기술개발사업
- IND submission in 2023

Vaccine Patch



RapVac-2302
Hepatitis B

rHBsAg



- HBsAg 탑재 마이크로니들 패치 백신동물 효능평가 완료
- 2022년 인도 Serum institute 원료공급 계약

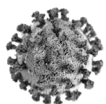


RapVac-2301
Influenza

Cell based purified HA

In-house

- 2022년 글로벌백신기술지원사업
- 2024년 제제연구 및 효능평가 완료
- 2025년 임상 진입

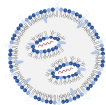


RapVac-2004
SARS-CoV-2

DNA vaccine



- 에이비온 공동연구 (RIGHT FUND)
- *in-vivo* 효능 및 challenge test 완료



RapVac-2101
SARS-CoV-2

rTrivalent RBD



- *in-vivo* 효능 평가 완료

Influenza

mRNA vaccine

In-house

- *In-vivo* PoC



Innovative Microarray Drug Delivery System

라파스 마이크로니들 주요 의약품 및 백신 시장 규모 및 사업화 전략

파이프라인

글로벌 시장 규모

개발 일정 및 사업화 전략



RapMed-1506
면역치료제

2020년 USD 33.1B → 2026년 USD 45.4B
(450억 달러)

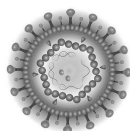
- 주요 시장 : 미국, 유럽, 일본
- 24년 1상 완료
- 25년 Licensing out



RapMed-2003
당뇨/비만 치료제

2021년 USD 3.2B → 2030년 USD 100B
(약 1,000억 달러)

- 24년 임상 1상 완료
- 라이선싱 아웃 (Multinational Company)
- 30년 Launching



RapVac-2302
Hepatitis B

2022년 USD 3.3B → 2032년 USD 5.7B
(약 30억달러)

- 25년 임상 1상 진입
- 25년 Serum Institute 시장 확대 협의
- 26년 국내 인허가 진행
- WHO PA 진행



RapVac-2301
Influenza

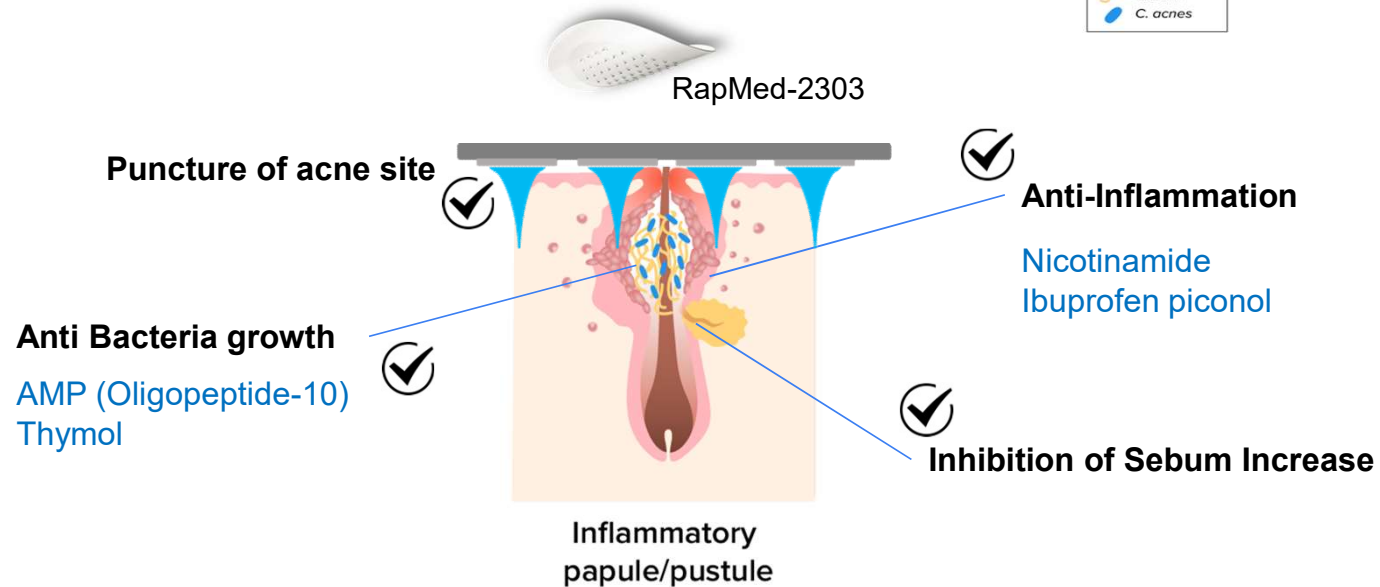
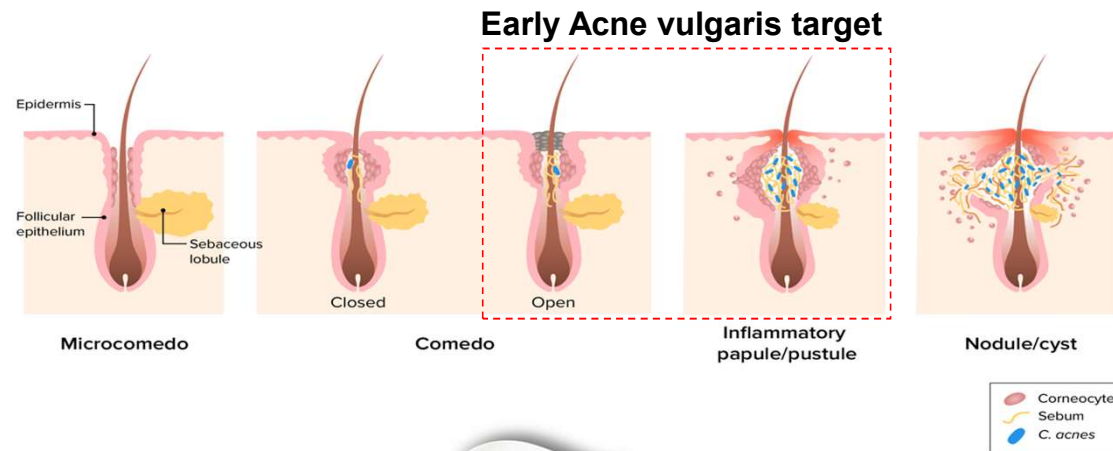
2020년 USD 60M → 2030년 USD 101.27M
(약 0.8억달러)

- 25년 단가 A/H1N1 임상 1상 진입 (First human Clinical trial, PoC)
- 26년 Dose sparing test
- 26년 3가 백신 임상 진입

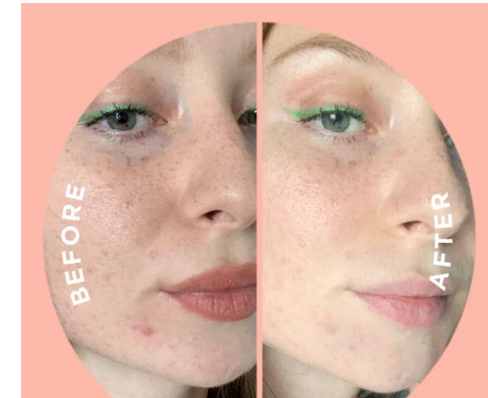


Innovative Microarray Drug Delivery System

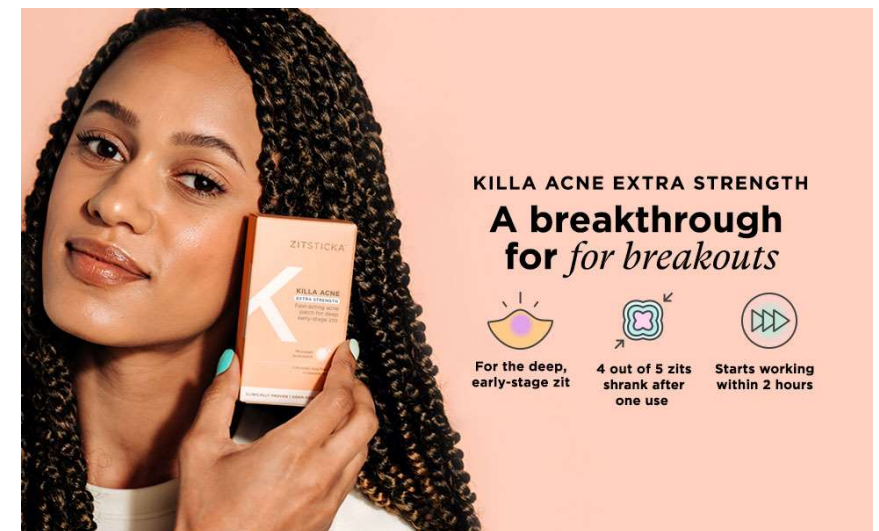
여드름 치료제



여드름 치료제



- Brand holder : ZitSticka, USA
- Product NDC : 81746-417
- Marketing Status: OTC monograph final
- Active Ingredient : 2% Salicylic acid
- Inactive ingredient : Nicotinamide, Oligopeptide-10
- Completed Inspection by US FDA**
- Launching date : 2023. 4.**

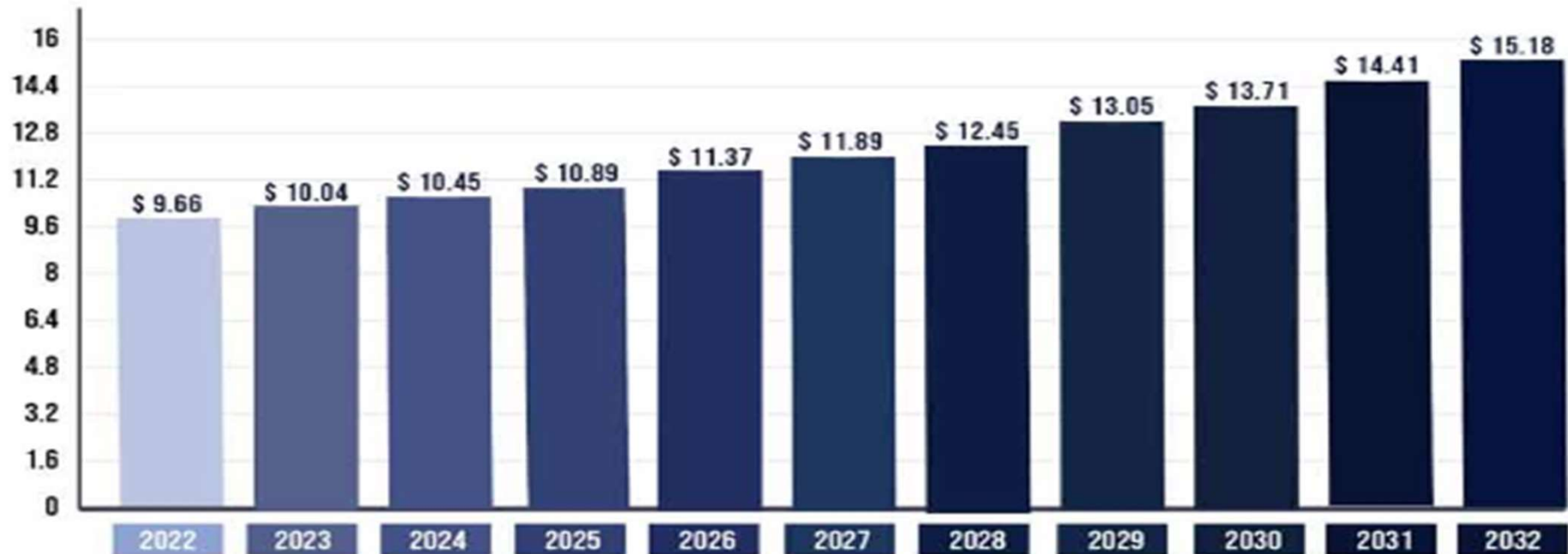


Innovative Microarray Drug Delivery System

여드름 치료제

PRECEDENCE
RESEARCH

ACNE TREATMENT MARKET SIZE, 2022 TO 2032 (USD BILLION)

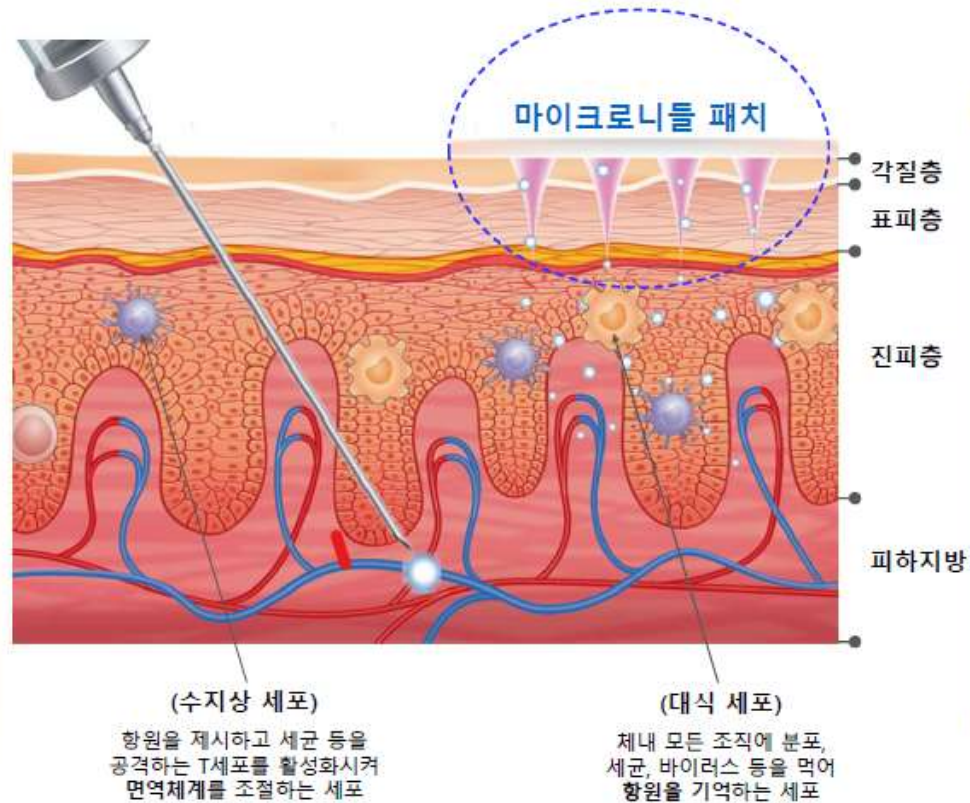


글로벌 여드름 치료제 시장 규모는 2022년 기준 USD 9.66B 이며 2032년 까지 CAGR 4.8%를 예상하여, 약 USD 15.18B 까지 확대될것으로 예상. (ref. Acne treatment market, PRECEDENCE RESEARCH)

피하주사 면역치료제 대비 마이크로니들 패치 면역치료제의 장점

(주사제)

- 근육층에 약물투여 (면역유도능 ↓)
- 생물학적 약물의 액체 상태 유통과정에서 냉장 유통이 필요, 이에 따른 선진국 위주 공급
- 보관 및 투약을 위해 전문의료시설, 전문의료진 필수
- 항원이 급격하게 주입되고 전신으로 확산됨으로 부작용 발생 가능성이 높음



(마이크로니들 패치)

- 면역세포가 풍부한 진피층에 직접 약물 전달, 약물 손실량 최소화 및 전달을 극대화
- 고형화 제제로 상온유통이 가능, 저개발 도상국의 공급격차를 해소
- 전문의료진의 도움 없이 언제 어디서나 쉽게 부착 가능
- 피부 수분에 의해 서서히 녹아 진피층에 용해된 적은 양으로도 안전하게 항원을 전달하는 면역 유도능 보유

➤ 연구결과 1. Biomaterials 150 2018, 38-48



Successful transdermal allergen delivery and allergen-specific immunotherapy using biodegradable microneedle patches

Ji Hye Kim ^{a,1}, Jung U. Shin ^{a,1}, Seo Hyeong Kim ^{a,b}, Ji Yeon Noh ^a, Hye Ran Kim ^a, Jungsoo Lee ^a, Howard Chu ^a, Kyoung Yong Jeong ^c, Kyung Hee Park ^c, Jung Dong Kim ^d, Hong Kee Kim ^a, Do Hyeon Jeong ^d, Tai-Soon Yong ^a, Jung-Won Park ^c, Kwang Hoon Lee ^{a,b,*}

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^d Rapheal, South Korea

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Successful transdermal allergen delivery and allergen-specific immunotherapy using biodegradable microneedle patches

Both MNIT (10 µg) and SCIT (100 µg) treatments improved clinical and histologic manifestations of AD: skin lesions, altered immunoglobulin production, dampened Th2 cellular response, and boosted Treg infiltrates, without significant side effects; whereas SCIT (10 µg) or placebo subsets failed to show any effects. Based on the favorable safety and efficacy profiles demonstrated in mice by MNIT in the current study, we believe that MNIT may serve as a new SIT modality.

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1. Introduction

Despite numerous treatment modalities that are available for allergic diseases, allergen-specific immunotherapy (SIT) is advantageous in that it is a disease-modifying, causal treatment that induces long-lasting tolerance to allergens [1].

Atopic dermatitis (AD) is a chronic, relapsing, inflammatory skin

disease that affects 20% of children and 1–3% of adults [2,3]. Recently, SIT has received support in treating AD, backed by randomized controlled trial [4] as well as meta-analyses [5], and especially by its success in patients sensitized with house dust-mite allergen, the most commonly sensitized allergen in atopic dermatitis patients [6–8]. There are several routes for SIT. Subcutaneous immunotherapy (SCIT) is the most commonly used and generally effective route for allergen injection. However, the need for frequent visits over a long period has undermined patient adherence. To overcome this limitation, sublingual immunotherapy (SLIT), which delivers allergen via mucosal layer, has been developed. However, effectiveness of SLIT is less certain than that of SCIT [9,10]; therefore, a more effective, safe, and convenient method for allergen delivery is needed.

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The two authors contributed equally to this work and should be considered as first authors.

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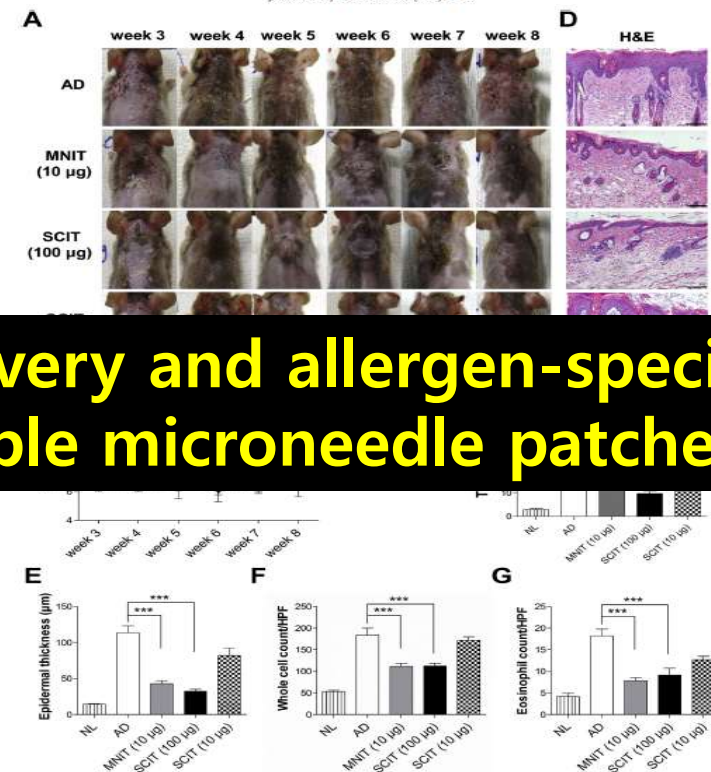
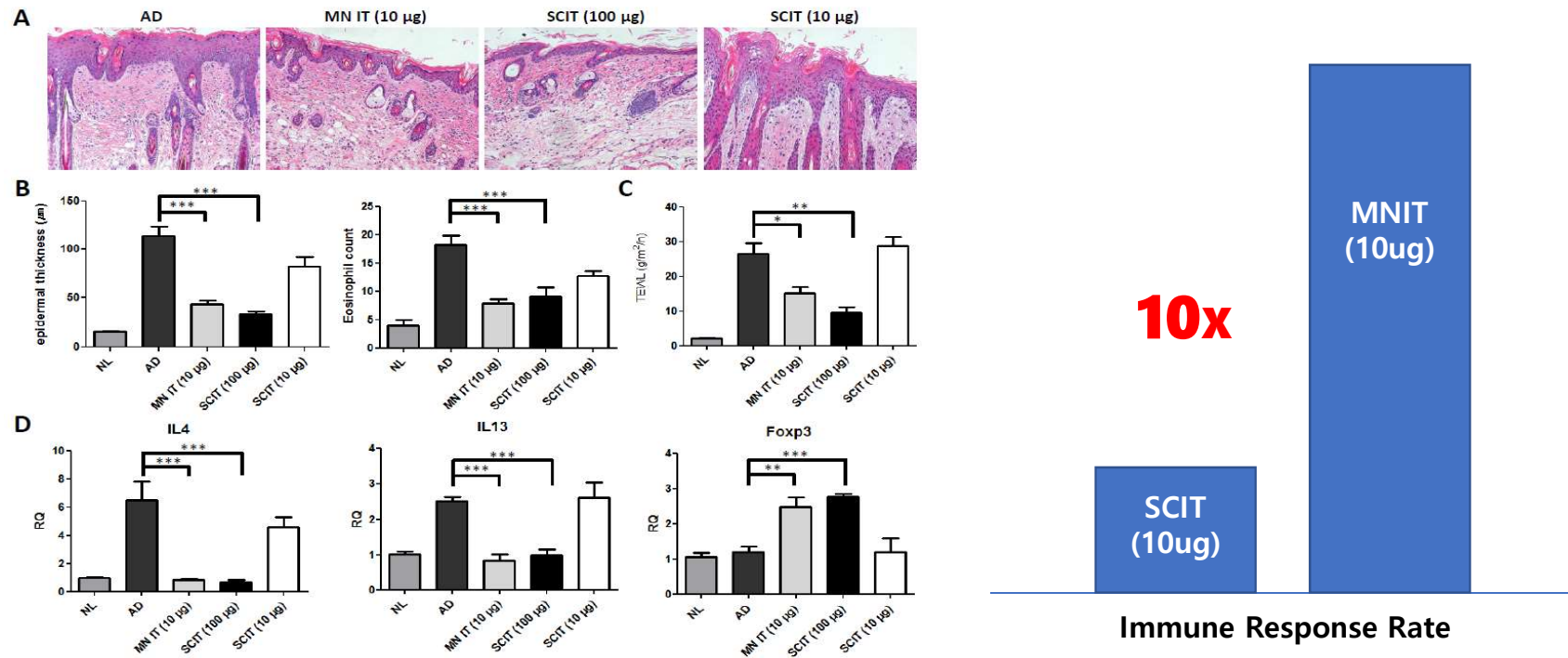


Fig. 4. Clinical and histologic features of AD-induced mouse model of SIT. (A) Changes in clinical appearance of skin, Weeks 3–8 (dermatitis noted since Week 3); (B) SCORAD, Weeks 3–8 (*AD vs MNIT 10 µg; #AD vs SCIT 100 µg); (C) TEWL measured at Week 8 (* $P < 0.05$, ** $P < 0.01$); MNIT (10 µg) and SCIT (100 µg) subsets showed clinical improvement, compared to AD and SCIT (10 µg) subsets; (D) H&E-stained mouse skin (bar = 100 µm); (E) Epidermal thickness; and (F) Total and (G) eosinophil cell counts (* $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$); AD, atopic dermatitis; SIT, allergen-specific immunotherapy; SCORAD, Scoring AD; MNIT, microneedle immunotherapy; SCIT, subcutaneous immunotherapy; TEWL, transepidermal water loss.

Clinical and histologic features of AD-induced mouse model



“마이크로니들을 이용한 투약군이 동량의 피하주사 투약군보다 탁월하게 좋은 면역치료 지표를 보여줌”

➤ 연구결과 2. Clin Exp Allergy 2020;00:1–9.

Received: 22 March 2020 | Revised: 21 May 2020 | Accepted: 8 June 2020
DOI: 10.1111/cea.13688



ORIGINAL ARTICLE

Experimental Models of Allergic Disease

Efficacy of transdermal immunotherapy with biodegradable microneedle patches in a murine asthma model

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Kyoung Yong Jeong² | Ji Hye Kim⁵ | Chang Ook Park^{1,2,5} | Sung-Ryeol Kim^{1,2} |
Jae-Hyun Lee^{1,2} | Do Hyeon Jeong^{3,4} | Tai-Soon Yong⁶ | Kwang Hoon Lee^{4,5} |
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Funding information:
This research was supported by Korea Health Technology R&D Project through the Korea Health Industry Development Institute and the Ministry of Health & Welfare, Republic of Korea (H14C1324) and by a faculty research grant of Yonsei University College of Medicine (6-2019-0054).

Objective: To overcome the weak points of conventional AIT, we developed a HDM loaded biodegradable microneedle patch (MNP) for transdermal immunotherapy (TDIT). We aim to demonstrate the efficacy of TDIT in murine asthma model triggered by HDM compared with conventional SCIT.

Methods: To make HDM asthma mouse model, 5-week-old BALB/c female mice were sensitized and challenged by intranasal administration of HDM. The mice were divided into 5 groups: sham, asthma, low (10 µg) and high dose (100 µg) SCIT, and TDIT (10 µg). To make HDM loaded MNP, droplet-born air blowing method was used. Airway hyperresponsiveness and allergic inflammation markers were analysed by bronchoalveolar lavage fluid, immunohistochemistry, serum immunoglobulin (Ig) analysis, and lung cytokine assays.

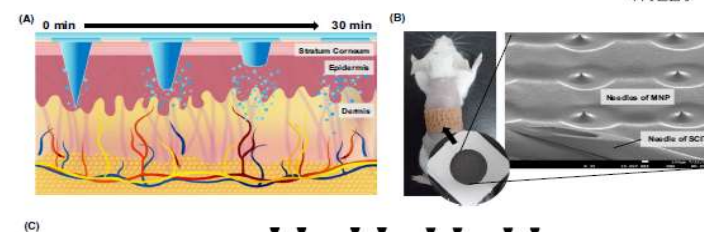
Results: Airway hyperresponsiveness was ameliorated by TDIT. Eosinophilic inflammation in bronchoalveolar lavage was improved without adverse reactions. Reduction of Th2 (IL-4, IL-5, and IL-13) cytokines, and HDM-specific IgE, induction of Treg (IL-10, TGF-β), Th1 (IFN-γ) cytokines were observed. Eosinophilic infiltration, goblet cell hyperplasia, and subepithelial fibrosis were also alleviated by TDIT. These changes were more significant in the TDIT group than in subcutaneous AIT group.

Conclusion: In conclusion, HDM loaded biodegradable TDIT is a novel treatment option to treat asthma which showed more effectiveness and may have better safety profiles than conventional SCIT.

KEYWORDS
allergen immunotherapy, asthma, house dust mites, mice, microneedle

PARK ET AL.

WILEY | 3



bronchial challenge with low to high concentrations (0, 3.125, 6.25, 12.5, 25.0, and 50.0 mg/mL) of methacholine (Sigma-Aldrich). After anaesthesia was administered, a tracheostomy was performed, followed by cannulation and ventilation, as previously described.¹⁴

2.4 | Bronchoalveolar lavage fluid analysis

After measuring AHR, bronchoalveolar lavage fluid (BALF) was collected through the tracheal cannula using Hank's Balanced Salt Solution (HBSS; Gibco). BALF was centrifuged for 3 min at 1500× g and 4°C. Whole cells were resuspended in HBSS and counted using a haemocytometer. Cells were smeared on slides using cytocentrifugation (Cytospin 3; Thermo). The slides were stained with haematoxylin and eosin (H&E), and 200 inflammatory cells (eg, neutrophils, eosinophils, lymphocytes, and macrophages) were counted.

2.5 | Cytokine analyses and immunohistochemistry

To assay cytokines, the right lung was homogenized in 1.5 mL RIPA buffer (Thermo) containing a protease inhibitor solution (Sigma-Aldrich) using TissueLyser II (Qiagen). Lung homogenates were centrifuged at 14 000× g for 20 min. Supernatants were collected and stored at -20°C. Concentrations of interleukin (IL)-4, IL-5, IL-13, IL-33, thymic stromal lymphopoietin (TSLP), interferon (IFN)-γ, transforming growth factor (TGF)-β, and IL-10 were measured using an ELISA kit (R&D Systems; DuoSet), according to the manufacturer's

instructions. The optical density at 450 nm was obtained using a VersaMax microplate reader (Molecular Devices).

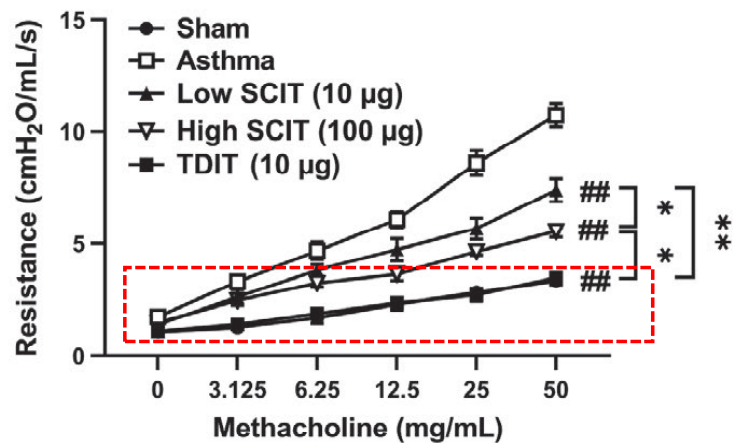
To analyze histological and immunohistochemical changes, the left lung was fixed in 10% formalin for 24 hours and embedded in paraffin. Paraffin-embedded sections were sliced at a thickness of 3–4 µm and stained with H&E and periodic acid-Schiff (PAS) to identify goblet cell hyperplasia. Staining with Masson's trichrome (MT) was used to assess fibrosis. Each stained slide was photographed under an upright microscope (BX53F; Olympus) equipped with a digital camera (U-TV0.63XC; Olympus). Additionally, quantification was conducted using Metamorph software (Molecular Devices).

Briefly, PAS-stained slides were placed under a light microscope at 200× magnification. Goblet cells in the selected bronchi were counted. Finally, goblet cells per micrometre of basement membrane were calculated and analysed statistically. The area of fibrosis was measured using the colour pixel count over the preset threshold colour for the entire field, which contained several bronchovascular bundles.

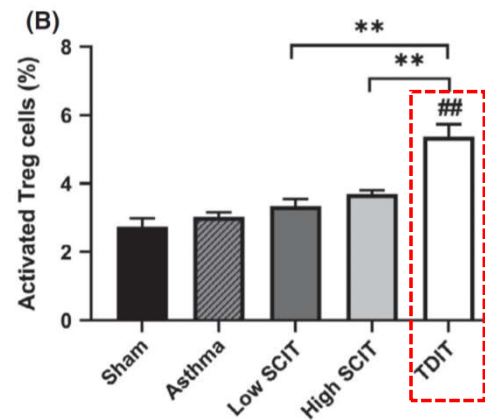
2.6 | Analyses of serum immunoglobulins (Igs)

We measured *D. farinae*-specific serum IgE and IgG2a levels using the indirect ELISA method. *D. farinae* extracts (10 µg, 1 µg/µL) were used to coat the wells of the microplates (Corning #9018; Corning) and stored at 4°C overnight. The ELISA reagents were purchased from BD Biosciences (BD OptiEIA Reagent Set B: BD, 550534).

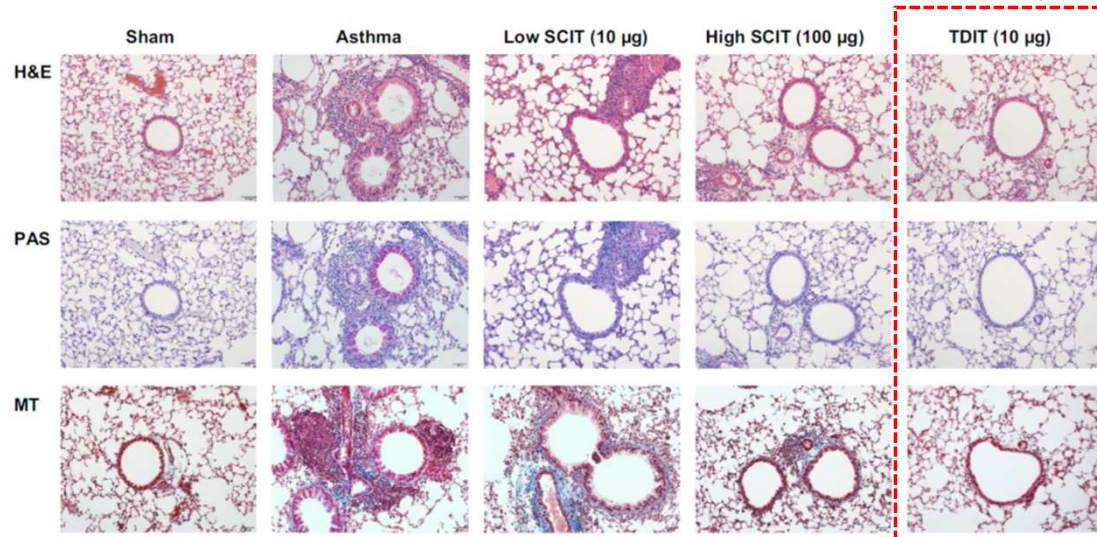
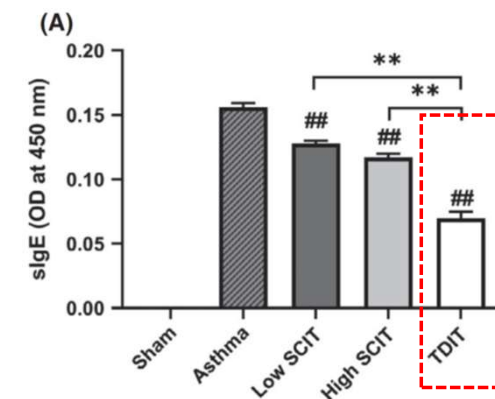
라파스 마이크로니들 패치 면역치료제의 *In-vivo* 효능 결과



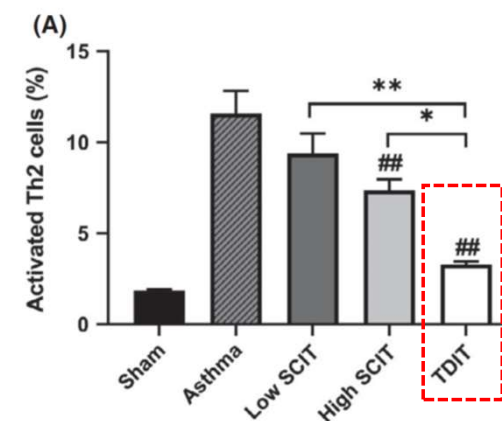
① Treg activation



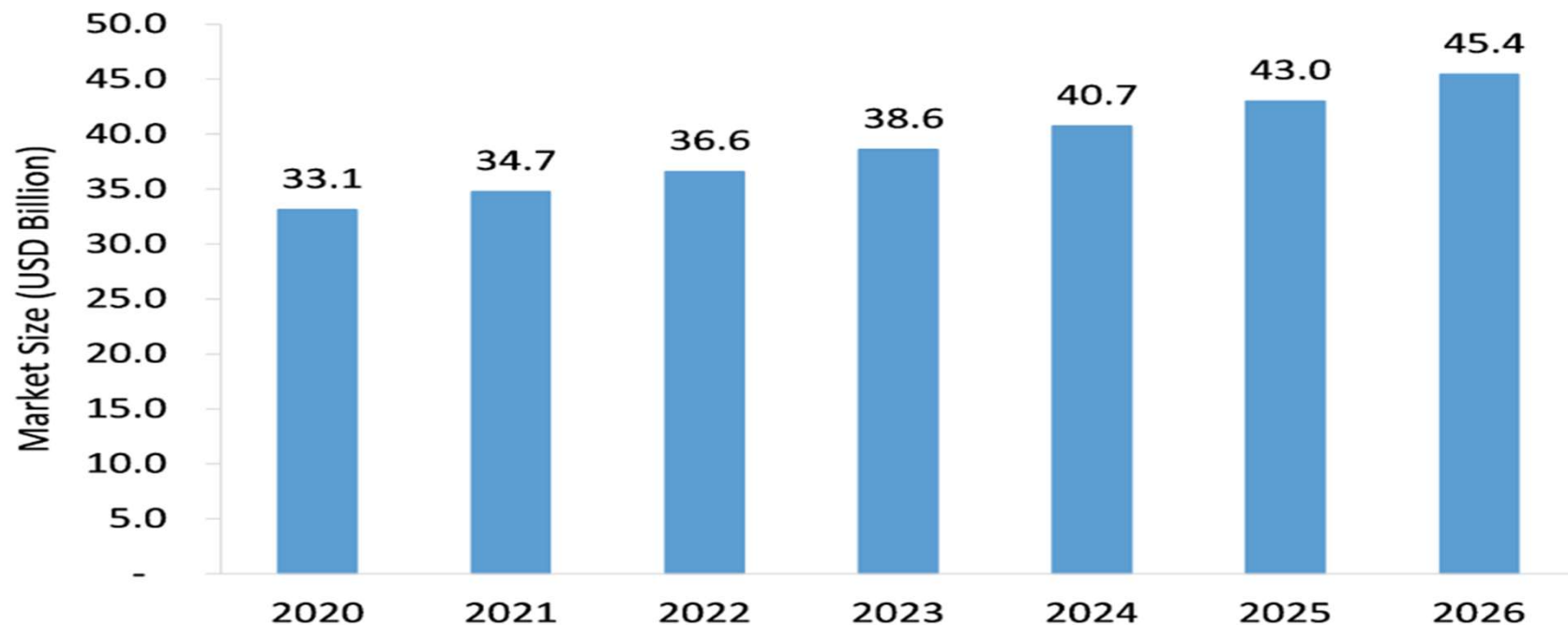
② IgE reduce



③ Th2 reduce



RapMed-1506, 면역 치료제



알러지질환 진단 및 치료제 시장 규모는 2020년 기준 USD 33.1B 이며, 2026년 까지 USD 45.4B 를 확대 되어, CAGR 5.5%를 예상 (Allergy Diagnostic and treatment market report, Startview research)

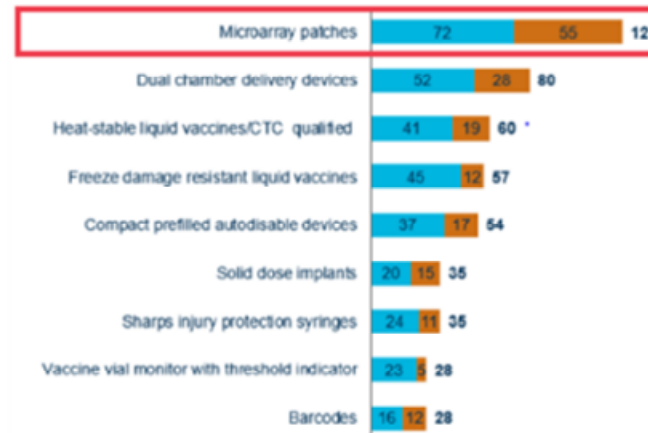
국내 혈관운동성 및 알레르기성 비염 환자와 알레르기성 접촉피부염 외래환자는 약 930만명으로 집계되며, 국내 알레르기 치료제 시장 규모는 약 1600억원 규모임 (메디포뉴스 보도자료, 2023.02.03)

Global Situation of Microneedle Patch Vaccine



Vaccine microarray patches (MAPs): *public summary of the VIPS Alliance Action Plan*

Innovations' ranking



PRIORITY LIST of vaccine targets for MAPs

Hepatitis B virus

Measles, rubella (MR)/ Measles, mumps and rubella (MMR)

Human papillomavirus

Rabies virus

Yellow fever

Influenza virus, seasonal and pandemic

SARS-CoV-2

Group B streptococcus (GBS), S agalactiae

Neisseria meningitidis A,C,W,Y,(X)

Salmonella Typhi

Streptococcus pneumoniae

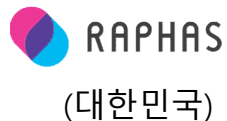


Innovative Microarray Drug Delivery System

Global Situation of Microneedle Patch Vaccine

Formulation

Prototype in Lab



독감 백신
B형 간염백신



GLP-1
(semaglutide)



Innovative Microarray Drug Delivery System



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Vaxxas Initiates Phase I Clinical Study of First Needle-Free, Inactivated Seasonal Influenza Vaccine

- Vaxxas' proprietary HD-MAP technology produces products that are easy to use (potentially reducing the complexities and costs associated with traditional injectable vaccines)
- The vaccine being delivered by the Vaxxas seasonal flu vaccine (IIV4) targeting influenza virus targeted in any given year and encompass two strains of influenza
- This Phase I clinical study will include

February 09, 2023 07:00 PM Eastern Standard Time

CAMBRIDGE, Mass. & BRISBANE, Australia-- commercializing a novel vaccination platform, the inactivated seasonal influenza vaccine quadrivalent patch (HD-MAP) technology.

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Micron Biomedical Announces Positive Measles and Rubella Vaccination Results from First Clinical Trial of Microarray Injection-Free Vaccine Delivery in Children



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Vaxess Announces Results from Completion of MIMIX-Flu Vaccine Patch Phase 1 Trial

June 4, 2023

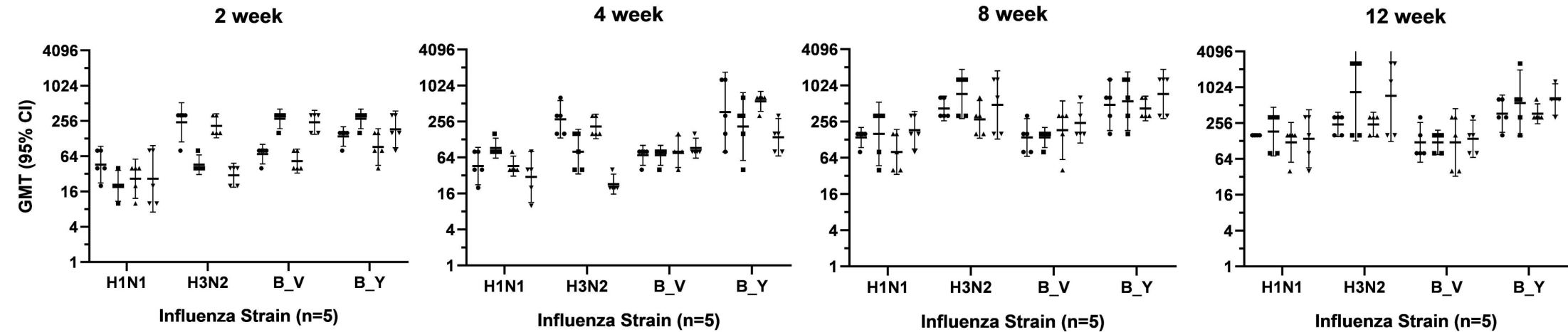
CAMBRIDGE, Mass. — Vaxess Technologies, Inc., a life sciences company developing a shelf-stable vaccine patch with potential for self-application, today announced results from the phase 1 trial completion of VX-103, a seasonal influenza vaccine patch.

The trial, conducted in 45 healthy patients, evaluated delivery of an H1N1 influenza antigen from Vaxess's partner, GC Biopharma Corp., delivered via the Vaxess MIMIX™ Patch. Vaxess enrolled healthy adult volunteers ages 18-39 to evaluate the safety, reactogenicity, tolerability, and immunogenicity profiles for two influenza vaccine dose levels, fractional H1 vaccine dose level 7.5 µg and standard H1 vaccine dose level 15 µg vs placebo. Vaxess also evaluated the durability of the immune response for each vaccine dose level, and assessed the breadth of the influenza A H1 antigen responses.

RapVac-2301, 인플루엔자 백신

- Animal: SD-Rat
- Hemagglutinin 중화항체 역가 : 접종 후, 8-12주 경과 후 2주차 대비 약 4배 이상 증가
- Hemagglutinin Inhibition Assay

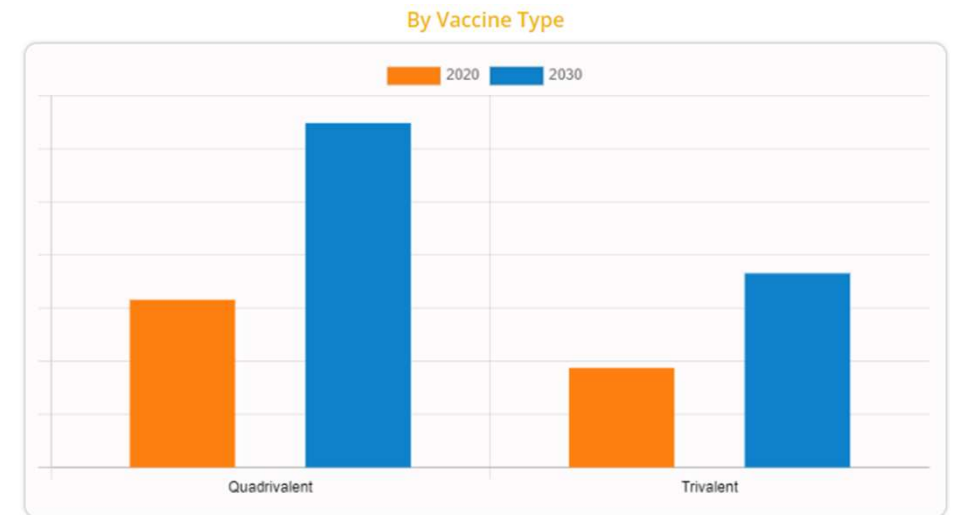
- MAP(Quad)
- MAP(Mono)
- ▲ Injection(Quad)
- ▼ Injection(Mono)



GMT : Geometric Mean Titer of Hemagglutinin Inhibition Assay

인플루엔자 항원 탑재 마이크로니들 패치 백신의 주사 대비
비열등한 바이러스 중화 능 (HIA GMT) 확인

RapVac-2301, 인플루엔자 백신

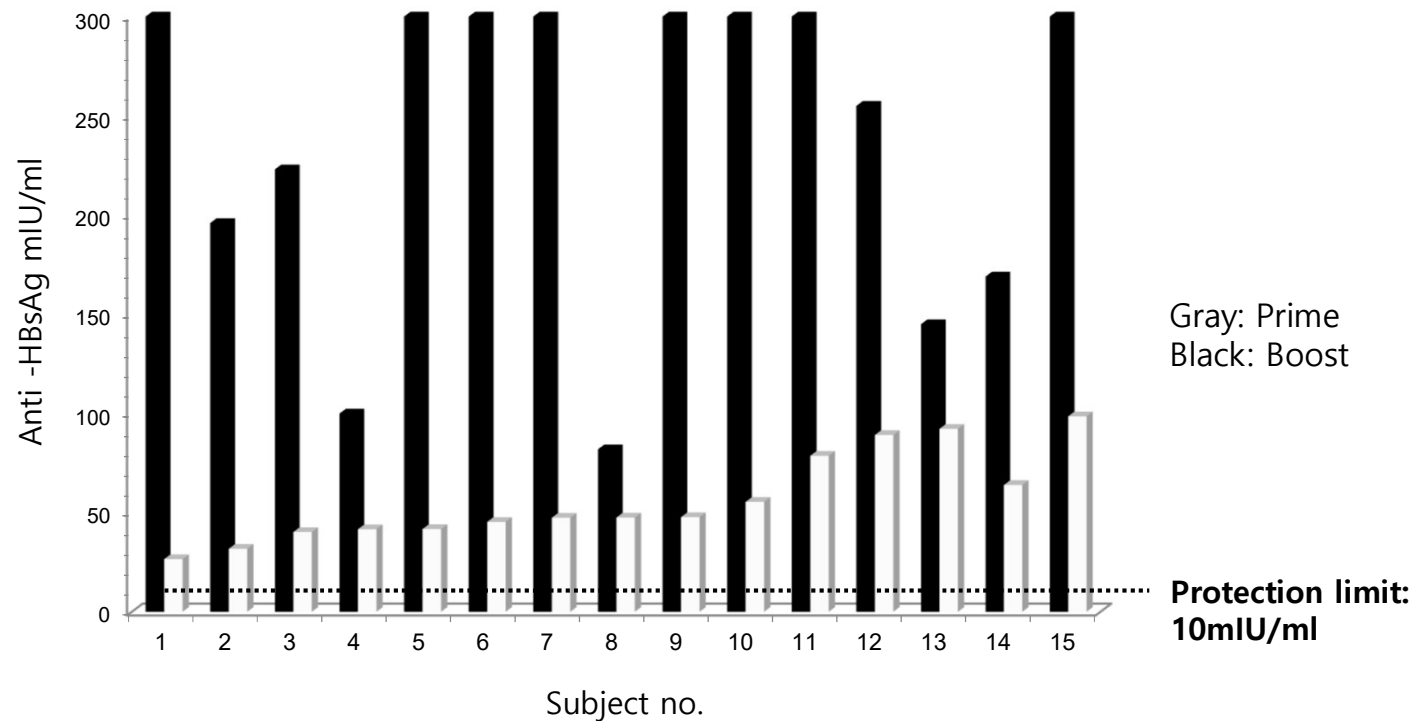


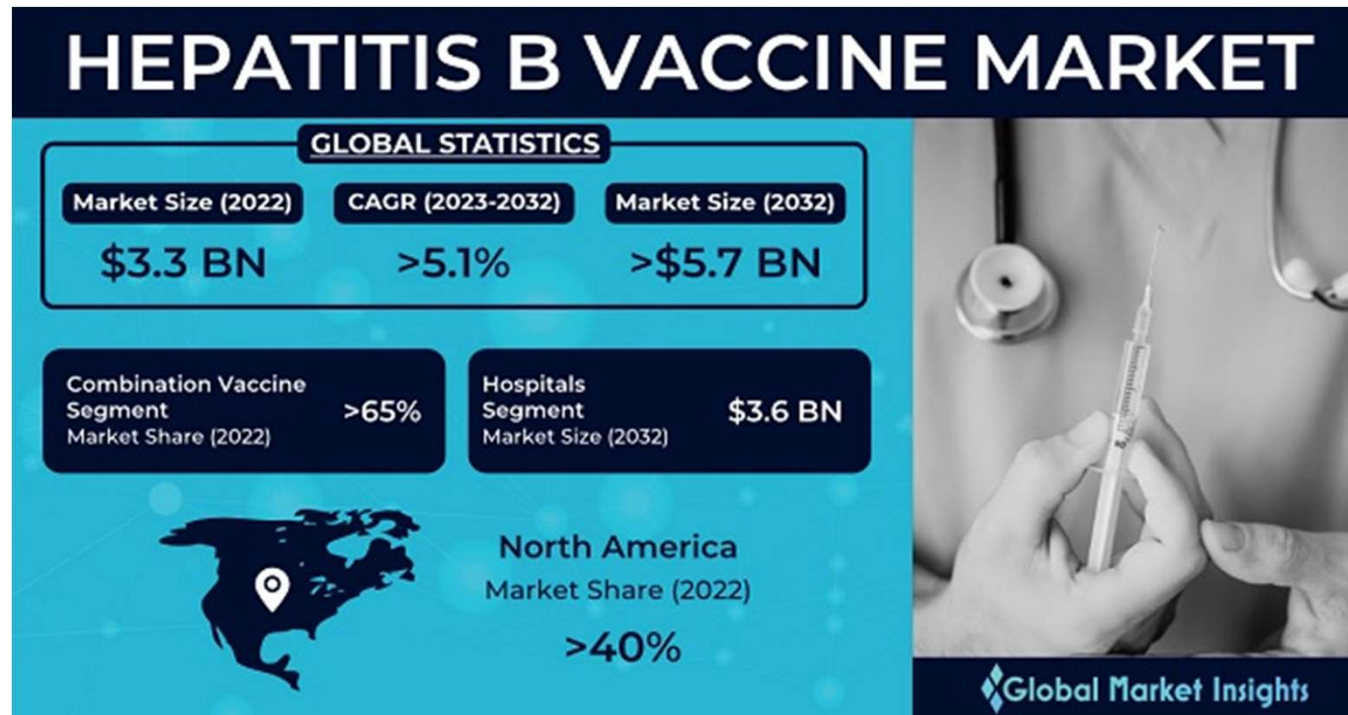
미국 시장조사 기관 'Allied market Research(2021)'에 따르면 전 세계 인플루엔자 백신 시장 규모는 2020년 60억 달러에서 연평균 7.2% 성장률을 기록하며 2030년 100억 달러로 성장할 것으로 예측 됨

Ref. Influenza Vaccine Market by Vaccine Type (Quadrivalent and Trivalent), Technology (Egg-based, and Cell culture), Age Group (Pediatric, and Adult), and Route of Administration (Injection, and Nasal Spray): Global Opportunity Analysis and Industry Forecast, 2021-2030, Allied market Research

RapVac-2302, B형 간염백신

- Raphas HBsAg 탑재 마이크로니들 패치 제조, Serum Institute 에서 면역 유도능 시험을 통한 백신 효능 검증
- Animal: Mouse
- 혈청 내 HBV sIgG 역가 확인
 - Prime 및 boost 접종에 의한 우수한 항체형성.
 - Prime접종만으로 바이러스에 최소 보호 항체 역가인 10mIU이상의 sIgG 역가 확인





B형간염 백신의 글로벌 시장 규모는 USD 3.3B 이며 2032년까지 CAGR 5.1% 를 예상하여 USD 5.7B 까지 확대될 예정임 (Hepatitis B Vaccine Market, Global Market Insights)

Semaglutide (Rx)

1. Type 2 Diabetes Mellitus (제2형당뇨)

- 1) SC Injection (Ozempic) : 최대 (유지) 용량 : 0.5 mg / qWeek
- 2) Oral tablet (Rybelsus): 14 mg /PO qDay (하루 한번 투약)

경구제형의 투약용량 (14mg)은 주사제 일일투약용량(0.07mg)의 200배 용량



Compliance 개선을 위한 개량신약 Rybelsus 개발
non Cost-effective formulation

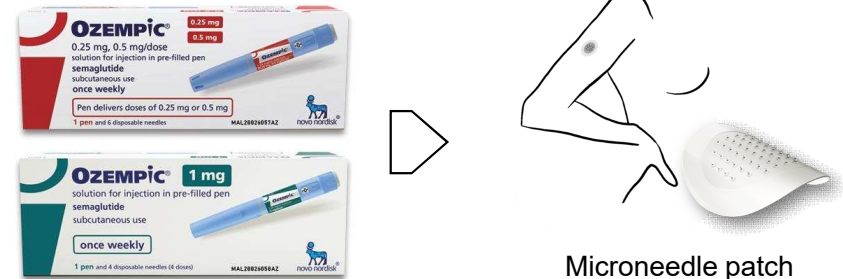
2. Weight Management (비만)

SC injection (Wegovy) 최대 (유지) 용량 : SC 2.4 mg / week, **Oral tablet 용량 없음**

3. 라파스/대원제약 "합성 Semaglutide microneedle patch"

임상 일일용량 0.45mg/patch 으로 주사제 1주일제형 대비 28% 증량 제제

(Micropig PK/PD simulation을 통한 임상용량결정)



Cost-effective formulation
Convenience, Low adverse effect

<https://reference.medscape.com/drug/ozempic-rybelsus-wegovy-semaglutide-1000174>

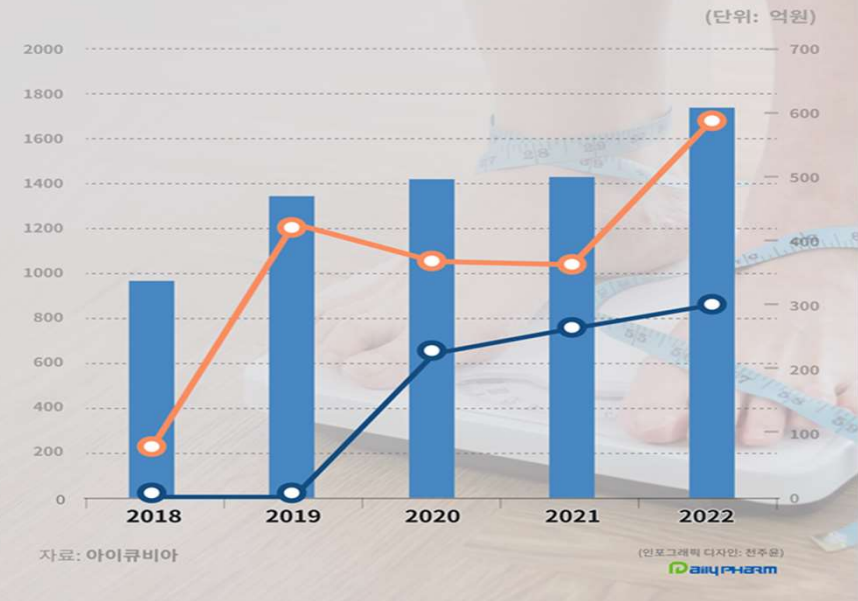
글로벌 비만치료제 시장 규모



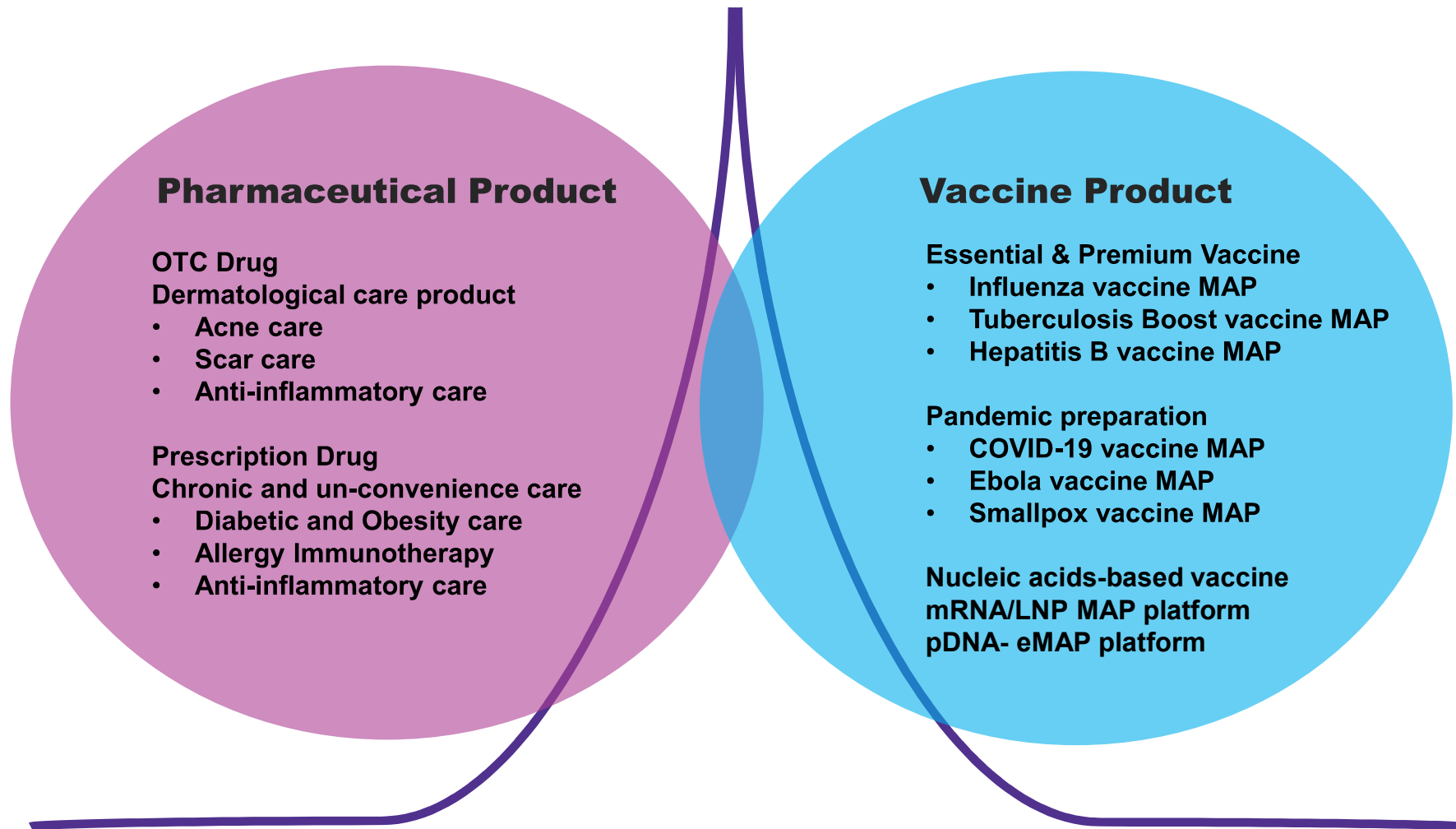
*자료: 시장조사기관 리서치앤리서치

한국바이오협회가 2022년 5월 23일자로 발간한 글로벌 비만치료제 개발동향에 따르면 세계 비만치료제 시장 규모는 2021년 32억 달러에서 2026년 46억 달러로 성장할 것으로 전망됨 (머니투데이 보도자료, 2022.07.05)

연도별 비만치료제 시장 규모(왼쪽)와 삭센다·큐시미아(오른쪽)



국내 비만치료제 시장 규모도 지난 2018년 968억 원에서 2022년 1757억 원으로 약 4년 만에 무려 81.5%나 증가. 그 중 삭센다의 22년 매출은 589억원으로 전년대비 62.7% 증가 하였으며, 발매 이후 17분기 연속 매출 1위를 차지하고 있음.(데일리팜 보도자료, 2023.03.03)



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Microneedle patch global leader