OBJECTIVES

1. To be familiar with the key dermatological therapeutics of 2016

2. To translate this information into changing clinical practice
### DISCLOSURES

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<thead>
<tr>
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<th>Pierre Febrre</th>
<th>Basilea</th>
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<tbody>
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<td>EMD Serono</td>
<td>Astellas</td>
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<td>Global Trox</td>
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<td>Celgene</td>
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<td>(DQTC)</td>
<td>PremPharm</td>
<td>Berlex</td>
<td>Leo Pharma</td>
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<td>Innovaderm</td>
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<td>Centocor</td>
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<td>Barrier</td>
<td>Janssen</td>
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<td>Dravis</td>
<td>NanoBio</td>
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<td>Westwood Squibb</td>
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**Dr. Charles W. Lynde, MD, FRCPC**
Please note that this presentation does contain some discussion of “off-label” uses for pharmaceutical products.
BOLDLY GOING WHERE NO DERMATOLOGIST HAS GONE BEFORE.
HOTTTEST AREA

... Atopic Dematitis
A PARADIGM SHIFT IN AD

Bieber, T. Atopic Dermatitis: New Frontiers, unmet therapeutic needs and treatment advances. WCD. 2015
NEW TARGETS IN AD

• Anti-PDE4 (crisaborole, apremilast)
• Anti-IL-17s
• Anti IL12/23 (ustekinumab)
• Anti-TNFs
• Anti-TSLP* (AMG 157)

• IL-4/13 blockers (dupilumab)
• Anti-IL-5 (mepolizumab)
• Anti-IL-6 (tocilizumab)
• Anti-IgE (omalizumab, ligelizumab)
• Anti-IL-22
• Anti-IL-31

Presented at EADV 2016; Session D1T11.1.
**Approval Timeline Pipeline Compounds of Interest**

*Filing dates are rough estimates based on best-case scenarios and progress to date.
** Note that dates are estimates for the US market.
*May have failed PII; incomplete data released

**SC / IV**
- Dupilumab (Regeneron)
- Nemolizumab (Chugai/Galderma)
- Lebrikizumab (Roche)
- Tralokinumab (AZ/LEO)
- Ustekinumab (Janssen) Japan only – pilot at Rockefeller
- Tezepelumab (AZ/Amergen)
- GBR30 (Glenmark Pharmaceuticals)
- ZPL-389 (Ziarco)
- Fevipiprant (QAW039)
- Baricitinib (Lilly)
- OP-15406 (Medimetriks)
- VTP-38543 (Vitae/Allergan)

**Oral**
- Crisaborole (Anacor)

**Topical**
- Il-4,13
- IL-13
- IL-12/23
- Linoleic acid
- TSLP
- OX40 antagonist
- CRTh2 receptor antagonist
- Histamine H4 receptor antagonist
- LXRβ agonist
<table>
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<tr>
<th>Drug</th>
<th>MOA</th>
<th>Phase</th>
<th>Route of Administration</th>
<th>Expected US Launch</th>
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<tr>
<td>Dupilumab</td>
<td>IL-4, IL-13</td>
<td>III</td>
<td>SC</td>
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<td>II</td>
<td>SC</td>
<td>2H 2019/2020</td>
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<td>SC</td>
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<td>CRTh2 Receptor Antagonist</td>
<td>II</td>
<td>Oral</td>
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<td>II (Japan)</td>
<td>SC</td>
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<td>II</td>
<td>Oral QD</td>
<td>2H 2020/1H 2021</td>
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<td>GBR30</td>
<td>OX40 antagonist</td>
<td>IIa</td>
<td>IV</td>
<td>2021</td>
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<tr>
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<td>Linoleic acid</td>
<td>IIb</td>
<td>Oral</td>
<td>2021</td>
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</table>
Indicated for: moderate-to-severe AD

**MoA:** IL-4, IL-13 inhibitor

Other indication being investigated: Asthma (Phase III), Eosinophilic (Phase II)

Launched: late 2016 (US)

**Canada launch: expected ~ late 2017**
LEBRIKIZUMAB (ROCHE)

Indicated for: moderate-to-severe AD

**MoA:** IL-13 inhibitors

Other indication being investigated: IPF, COPD, Hodgkin’s Lymphoma, Asthma

Launched: 2021 (US)
TEZEPELUMAB (MEDIMMUNE/AMGEN)

Indicated for: moderate-to-severe AD
Status: Phase II
MoA: human monoclonal antibody, inhibits TSLP (Thymic Stromal Lymphoprotein)
Other indication being investigated: Asthma
Launched: 2020? (US)
NEMOLIZUMAB (CHUGAI/GALDERMA)

Indicated for: moderate-to-severe AD
Status: Phase II
MoA: IL-31 inhibitor
Other indication being investigated: Asthma
Launched: late 2019 (US)
DS107G: RATIONALE

• DGLA (Dihomo-gamma-linoleic acid) & its metabolites
  • Have been shown to have anti-inflammatory effects
  • Purification technologies have advanced enough to allow the purification of GLA from plant oils, and then the conversion of GLA → DGLA by the addition of 2 carbons

TRALOKINUMAB

Partnership with AstraZeneca, LEO Pharma acquires the global licence to tralokinumab in skin diseases

an anti-IL-13 monoclonal antibody that delivered statistically significant improvements in Eczema Area and Severity Index (EASI) scores in patients with moderate-to-severe atopic dermatitis in a 12-week Phase IIb trial.

TOPICALS FOR ATOPIC DERMATITIS
PURPOSE: The purpose of this study is to determine whether AN2898 and AN2728 ointments are safe and effective treatments for mild-to-moderate atopic dermatitis (AD).

MoA: PDE4 inhibitor

Identifier: NCT01301508
GSK2894512 (GSK)

- *A Randomized, Blinded, Vehicle-Controlled, Dose-Finding Study of GSK2894512 Cream for the Treatment of Atopic Dermatitis*
- Status: Recruiting

**MoA:**
GSK2894512 inhibits the secretion of multiple pro-inflammatory cytokines and chemokines

*At present MoA is not completely understand*

EXCIPIAL (GALDERMA)
NEW LINE OF TOPICAL EMOLLIENTS & SKIN PROTECTANTS

• U4: 4% Urea Lotion
• U10: 10% Urea Lotion
• Repair: Enriched with 29.5% lipid content, Provitamin B5 and vitamin B3 and vitamin E together with emollients and skin conditioners to penetrate the skin deeply, relieving dry skin and protecting against external irritants.
• Protect: barrier cream, unscented, 5% aluminium chlorohydrate, parrafinum liquidum
• Bath & Skin Therapy Oil: light scent, vitamin E, almond oil, parrafinum liquidum

AD PATIENTS ARE ASKING FOR MORE NATURAL PRODUCTS...

In a survey of 1000 US Women in 2015 “The Green Beauty Barameter”

Survey: 54% of Women Want Skin Care to Be 'All Natural'

- When asked how important it was to purchase all-natural products among particular beauty categories, skin care came out on top, with 54% of women claiming it is important their skin care product purchases are all natural. This was followed by all-natural hair care at 49%, makeup at 40%, fragrance at 31% and nail care products at 26%.

ALL NATURAL PRODUCTS BY SKINFIX

- **SkinFix Body Repair Balm:**
  - **Product for atopic dermatitis free of:** acids, alcohols, cooling ingredients, essential oils, fragrance, parabens, phthalates, sulfates, scrubs

- **Eczema Regime for children:**
  - **Product for atopic dermatitis free of:** acids, alcohols, cooling ingredients, essential oils, fragrance, parabens, phthalates, sulfates, scrubs

PSORIASIS PATHOGENESIS

Canadian guidelines for the management of plaque psoriasis: overview.

Papp K¹, Gulliver W, Lynde C, Poulin Y, Ashkenas J; Canadian Psoriasis Guidelines Committee.

Collaborators (16)

Author information

Abstract
New clinical treatment guidelines for plaque psoriasis, written by a panel of 16 Canadian dermatologists, were recently published online. These Canadian Guidelines for the Management of Plaque Psoriasis are evidence based and free of any influence from corporate sponsors and have been endorsed by the Canadian Dermatology Association (CDA). The Guidelines offer treatment recommendations for mild and moderate to severe body psoriasis, as well as for psoriasis affecting specific areas of the skin, such as the facial, flexural, and genital areas; nails; scalp; and palms and soles. The present overview describes the genesis and contents of the Guidelines, which are available in full through the CDA at <http://www.dermatology.ca/guidelines/cdnpsoriasisguidelines.pdf> (English) or <http://www.dermatology.ca/french/psoriasisguidelines.html> (French).
IL-17 INHIBITORS

• Secukinumab
• Ixekizumab
• Brodalumab

SECUKINUMAB

- Indicated for moderate to severe adult PsO (other: uveitis, rheumatoid arthritis, ankylosing spondylitis)
- Fully human IgG1 anti-IL17A monoclonal antibody
- Standard dosing (subcutaneous injection): 300mg by injection
- **MoA:** selectively binds and neutralizes IL-17A
- Launched: March 2015

1. Cosentyx Product Monograph 2015
IXEKIZUMAB

- Indicated for adult moderate to severe PsO
- Humanized IgG1 anti-IL17A monoclonal antibody
- **MoA:** Selectively binds and neutralizes IL-17A
- Launched: August 2016
- Standard dosing (subcutaneous injection):
  - Week 0: 160 mg SC (ie, as two 80-mg injections), THEN
  - 80 mg SC q2wks at weeks 2, 4, 6, 8, 10, and 12, THEN
  - 80 mg SC q4wks
**BRODALUMAB**

- Indicated for moderate to severe PsO
- Fully human IgG2 anti-IL17Ra monoclonal antibody
- **MoA:** Inhibits activity of IL-17A, -F, -A/F, and –E (IL-25) by blocking receptor
- Launch: ≥ 2017
- Standard dosing (subcutaneous injection): 210mg

Brodalumab Product Monograph submitted to Health Canada 2016
In the partnership with AstraZeneca, LEO Pharma acquires the exclusive licence to Brodalumab in Europe.

LEO Pharma enters biologics through strategic partnership with AstraZeneca

*LEO Pharma is a significant step closer to realising its vision of becoming the preferred dermatology care partner following a strategic partnership with AstraZeneca announced today.*
IL-23 INHIBITORS

• Guselkumab (Janssen)
• Tildrakizumab (Merck/Sun Pharma)
• Risankizumab (Boehringer/AbbVie)
MECHANISM OF ACTION: USTEKINUMAB VS. GUSELKUMAB

BIOSIMILARS: WHAT ARE THEY?

• Copy version of original biologic whose data protection has expired
• Not a generic
• Not entirely identical
• Highly similar reference product re: physiochemical function characteristics/clinical performance
• Extrapolation of efficacy and safety data to other indications require scientific justification
• Risk management should be include plan for post-licensing surveillance
ABP501: HUMIRA BIOSIMILAR - AMGEN

• Data phase 3 program biosimilar Humira vs. Humira
• Primary endpoint: PASI improvement at week 16
• Switch to one another at week 50: same efficacy
• Immunogenicity: binding antibody/neutralizing antibody rates the same
• AE/SAE rates similar
• FDA approval Sept 20th 2016

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<thead>
<tr>
<th></th>
<th>Biosimilar</th>
<th>Humira</th>
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<tr>
<td>PASI 75</td>
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<td>PASI 90</td>
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<tr>
<td>PASI 100</td>
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IMPLICATION OF BIOSIMILARS FOR DERMATOLOGY PRACTICE

• Automatic Substitution
  • Dermatology standpoint should not be randomly changed
  • Impossible to assess loss of efficacy and adjudicate adverse events (AEs)

• Immunogenicity
  • All biologics (complete proteins) subject to this
  • Post marketing surveillance essential
  • Track potential AEs & lack of efficacy
APREMILAST (CELGENE)

- **Small-molecule PDE4 inhibitor**
  - For use in adults with active moderate to severe psoriasis and psoriatic arthritis
  - **Other uses** being investigated:
    - Rheumatoid arthritis, ankylosing spondylitis & Behcet’s disease

A multicentre, randomised, double-blind (sponsor-unblinded), placebo-controlled, repeat dose study to investigate the safety and tolerability, pharmacokinetics, pharmacodynamics, and efficacy of GSK2982772 in subjects with active plaque-type psoriasis.

Status: recruiting

MoA: GSK2982772 is a first-in-class, highly selective, receptor-interacting protein 1 kinase (RIP1) inhibitor being developed for the treatment of inflammatory disease conditions.
ENSTILAR (LEOPHARMA)

- Calcipotriol and betamethasone dipropionate aerosol foam
- Applied to the affected area once daily for 4 weeks Enhanced drug delivery and penetration vs Dovobet® ointment
- Superior efficacy compared to calcipotriol and betamethasone dipropionate alone & and calcipotriol + betamethasone dipropionate combination products (Dovobet gel and ointment)
- Fast and effective itch relief
- Safety and tolerability consistent with other fixed combination products. No clinically relevant impact on HPA axis and calcium homeostasis.
GSK2894512 CREAM (GSK)

• **A Randomized, Blinded, Vehicle-Controlled, Dose-Finding Study of GSK2894512 Cream for the Treatment of Plaque Psoriasis**

• Study status: **recruiting**

**MoA**

GSK2894512 inhibits leukotriene B4, tumor necrosis factor alpha (TNF-α), and T helper type 17 cells; inhibits molecules involved in the adhesion and recruitment of cells involved in the pathogenesis of psoriasis; and activates the aryl hydrocarbon receptor (AhR) and nuclear factorerythroid 2-related factor-2 (Nrf2) anti-inflammatory pathways.

ACNE
Guidelines

Management of acne: Canadian clinical practice guideline

Yuka Asai, MD MSc, Akerke Baiberganova, MD PhD, Maha Dutil, MD MEd, Shannon Humphrey, BSc MD, Peter Hull, MMed PhD, Charles Lynde, BSc MD, Yves Poulin, MD, Neil H. Shear, BASc(Hons) MD, Jerry Tan, BSc MD†, John Toole, BSc MD, Catherine Zip, MD
ACNE

• Have a large selection of topicals:
  • Retinoids
  • Benzoyl Peroxides
  • Combinations
  • Dapsone

... and now...
ADAPALENE AND BENZOYL PEROXIDE TOPICAL GEL, 0.3%/2.5% W/W (TACTUPUMP FORTE GALDERMA)

TactuPump Forte demonstrated significant reductions in inflammatory and non-inflammatory lesions in severe acne.
DRM01 targets key aspects of the acne pathophysiology not addressed by available topical therapies.
XEN801 TOPICAL GEL (XENON)

A Safety, Tolerability, Efficacy and Exposure Study of XEN801 Topical Gel

- **Study Design:**
  - A Phase 1 and 2 Randomized, Double-Blind, Vehicle-Controlled, Parallel-Group Study
  - Duration: 12 weeks
  - Status: Recruiting

MoA:
XEN801 is a potent and selective stearoyl-CoA desaturase-1 (SCD1) inhibitor.
CD5789 (GALDERMA)

- A Multi-Center, Randomized, Double-Blind, Parallel-Group Vehicle Controlled Study To Compare The Efficacy And Safety Of CD5789 50µg/g Cream Versus Vehicle Cream In Subjects With Acne Vulgaris
- Status: Recruiting

MoA (retinoid):
In vitro gene transactivation studies show a very high selectivity for RARγ over RARα and RARβ.

HORMONAL TREATMENT – BACK IN VOGUE?

• hormonal therapy offers an important treatment option for women with specific acne features
• Strongly consider a patient if: Has a condition associated with hyperandrogenism, has inflammatory acne involving the face and neck, has acne that flares up premenstrually
• Hormonal combination of: 2 mg cyproterone acetate and 0.035 mg ethinyl estradiol tablets (CLEO-35)
  • Indicated for women with severe acne

ROSACEA
ROSIVIER (GALDERMA)

- Ivermectin 1% cream, supplied in a 60g tube
- Dual action: anti-inflammatory & anti-parasitic
- Vehicle technology based on Cetaphil
- Indicated for the treatment of inflammatory lesions (papules and pustules) of rosacea in adults greater than 18 year of age
- 1x nightly application
- Better tolerated than azelic acid 15% and metronidazole 0.75%
VITILIGO

• Increased interest by a number of companies
• Currently there is an open-label pilot study exploring the use of Abatacept for the treatment of vitiligo
• MoA: a selective costimulation modulator, inhibits T cell activation and binds to CD80 and CD86 ?? MoA in Vitiligo
• Currently indicated for: rheumatoid arthritis
• (Bristol Meyers Squibb product) Orenicia – subcutaneous injection

HIDRADENITIS SUPPURATIVA

... and biologics
RESEARCH – APPLIED TO HIDRADENITIS SUPPURATIVA

OLD CONCEPTS
- Sweat gland disease
- Infection
- Acne spectrum

NEW CONCEPTS
- Follicular cysts = γ secretase
- Inflammasome activation = auto-inflammation, IL1
- IL17>TNFα (aberrant psoriasis)

OLD PARADIGMS
NEW PARADIGMS

OLD TREATMENTS
- Isotretinoin
- Antibiotics

NEW TREATMENTS
- Infliximab (2001), adalimumab
- Anakinra, canakinumab
- Ustekinumab
- Secukinumab, ixekizumab
- (CJM112 – NOVARTIS)
- Tofacitinib, baracitinib

‘NEW’ OLD TREATMENTS
- Methotrexate
- Cyclosporine, prednisone

courtesy of Dr. Jan Dutz
ALOPECIA AREATA
**TOFACTINIB**

- **MoA:** JAK Inhibitor

- Tofactinib for the Treatment of Alopecia Areata & Variants
  - 2 center, open-label, single arm trial using Tofactinib (5mg) was given 2x daily for 3 months
  - N = 66
    - 32% of patients experienced 50% or greater improvement in SALT score
    - 64% of patients responded to treatment

BARICITINIB (ELI LILLY/INCYTE)

- **MoA:** JAK 1 & 2 inhibitor
- Being developed orally & topically
- Exciting initial results

"Reversal of Alopecia Areata Following Treatment With the JAK1/2 Inhibitor Baricitinib." Reversal of Alopecia Areata Following Treatment With the JAK1/2 Inhibitor Baricitinib. 02 Nov. 2016.
TOPICAL INCB018424 (INCYTE)

• **Status:** active, not recruiting

• **Study design:**
  
  • An Open-Label (Part A) and a Double-Blind, Randomized, Placebo Controlled (Part B) Study, With an Open-Label Extension, of INCB018424 Phosphate Cream Applied

**MoA:**
JAK 1 & 2 Inhibitor
A Study of Secukinumab for the Treatment of Alopecia Areata

- Identifier: NCT02599129
- Status: recruiting
- 300 mg subcutaneous injections of Secukinumab vs. placebo
- MoA: IL-17 inhibitor

ALOPECIA AREATA

A Pilot Study of Tralokinumab in Subjects With Moderate to Severe Alopecia Areata

- **Identifier**: NCT02684097
- Phase 2
- **Status**: recruiting
- Randomized study 2:1 Tralokinumab to placebo
- **MoA**: IL-13 Inhibitor

ANDROGENIC ALOPECIA & OTHER ALOPECIAS?
REVITA (DS LABORATORIES)

• Revita (contains no sodium laureth sulfate, sodium lauryl sulfate that may irritate scalp tissue)
• It deploys natural cleansers; ingredients to increase scalp health
• It is recommended that in conjunction with a topical formulations allows users to address thinning with minimal cost and without any pain or intrusive procedures.

CHRONIC SPONTANEOUS URTICARIA
TREATMENTS: OMALIZUMAB

Humanized monoclonal IgG antibody against IgE
Low immunogenicity

BILASTINE

- MoA: high affinity for H1 receptor (antihistamine)
- Bilastine is indicated for the relief of the symptoms associated with chronic spontaneous urticaria (CSU) in patients 18 years of age and older.
- Standard dosing: oral tablet 20mg
- Launch: December 2016
BILASTINE

- Good cardiac safety profile
- H1-receptor occupancy in CNS equal to placebo
- It does not affect functional performance
- It does not affect the ability to drive even at double dose
- It does not potentiate alcohol and/or lorazepam effects
- Significantly better in terms of somnolence than cetirizine
RUPATADINE

- Released by PediaPharm in Canada in July 2016
- Rupatadine is a new second-generation antihistamine and platelet-activating factor (PAF) antagonist
- Currently available in 62 countries around the world
- High potency, good efficacy and excellent safety profile of the product have been demonstrated under an extensive clinical development program.
- Rupatadine (Tablet 10mg and Oral Solution 1mg/mL) is indicated for the treatment of the symptoms associated with Seasonal Allergic Rhinitis (SAR), Perennial Allergic Rhinitis (PAR) and Chronic Spontaneous Urticaria (CSU) in patients > 2 years of age

ONYCHOMYCOSIS

• Oral (adult)
  • Terbinafine: 250mg daily for 6-12 weeks
  • Itraconazole: 200mg daily for 6-12 weeks
  • Fluconazole: 200mg weekly for 9 months

• Topical
  • Echinaconazole (Jublia) once daily for 4-8 weeks
  • Preventative: ciclopirox olamine (Penlac) – poor success
MOB015B is a moderately viscous solution containing 10% terbinafine hydrochloride in a plastic tube with a silicon tip to facilitate application to the nail.

MoA: inhibits the biosynthesis of an integral component of fungal cell membranes

HSV-1 & HSV-2 SITAVIG (CIPHER)

- **Indicated for:** recurrent herpes labialis
- Acyclovir 50mg – Sitavig by CipherMuco-adhesive buccal tablet
- **MoA:** binds to viral DNA polymerase, terminates the DNA chain
- **A single dose of Sitavig reduced the viral load in the saliva 5-fold at the site of viral replication (P=.583),** possibly reducing the amount of virus available to return into latency.
ACTINIC KERATOSIS
ACTIKERALL (CIPHER)

- Topical antineoplastic agent, fluorouracil and salicylic acid, solution (0.5%/10%)
- indicated for the topical treatment of slightly palpable and/or moderately thick hyperkeratotic actinic keratosis (Grade I/II) of the face, forehead, and balding scalp in immunocompetent adult patients.

MoA:
- Inhibits thymidylate synthase
- Disrupts DNA & RNA synthesis

- Indicated in: infantile haemangioma
- Hemangiol (Pierre Fabre) – Propranolol hydrochloride, oral solution
- **MoA:** Beta blocker
- **Approval:** October 2016
Revanesse (Prollenium Medical Technologies)

- Cross-linked hyaluronic acid
- Canadian company (based in Aurora, Ontario)
- Revanesse dermal fillers have been proven to be safe and effective
- Contains no animal products
- Biocompatible and biodegradable
- Lower viscosity gel best used to fill superficial imperfections
- Indicated for: fine lines, forehead wrinkles—crow’s feet, perioral lines, labellar lines
- Duration (up to 9 months)
- Available with Lidocaine

MoA:
As a bile acid, deoxycholic acid emulsifies fat in the gut. Synthetically derived deoxycholic acid, when injected, stimulates a targeted breakdown of adipose cells by disrupting the cell membrane and causing adipocytolysis.
KEY TAKEAWAYS - TRENDS

• Increased understanding of immunology and potential targets for many of our diseases that we have poor treatments
• Better treatments for AD, vitiligo, alopecia areata
• PASI 90 & 100 for psoriasis
• Guidelines
• Cost containment? Biosimilars
“We are on the cusp of revolutionary new products that will change how we treat dermatologic diseases much like the biologics brought to our treatment of psoriasis.”

attributed to great philosopher also a dermatologist

~ CW Lynde
THANK-YOU

• A special thank-you to Ceilidh Welch