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Dermatologists Urged to Step Up Role in Antibiotic Stewardship

Dermatologists can and should play a larger role in antibiotic stewardship, according to researchers out of Perelman School of Medicine at the University of Pennsylvania in Philadelphia.

Data from the CDC shows the average dermatology provider wrote 669 antibiotic prescriptions in 2014, the most recent year for which data are available. That is, by far, the highest average of any provider specialty. For some perspective, the next closest group was primary care physicians, who wrote an average of 483 prescriptions per provider.

One reason the numbers might be higher is that dermatologists prescribe antibiotics both as pills and topical medications. If a patient is doing well on oral antibiotics for acne, you tend to not want to stop it. In fact, a recent New York University study found the average patient who is on oral antibiotics for acne will stay on the medication for 331 days, essentially a full year.

Topical antibiotics can also have long term effects on the communities of bacteria that live on the skin, potentially opening the door for colonization by an unwanted strain.

These same antibiotic drugs can also be used to treat community-acquired MRSA, Lyme disease, sexually transmitted diseases, and urinary tract infections. The stakes for resistance to these treatments are real. Even acne itself will become resistant over time.

Despite all of this data, dermatology remains in the background of the conversation on antibiotic stewardship.

Ebbing Lautenbach, MD, MPH, MSCE, Chief of Infectious Diseases, Perelman School of Medicine at the University of Pennsylvania, has a theory on why:

"A major focus of antibiotic stewardship is on areas where antibiotics aren't called for, where a doctor might write the prescription without thinking about why and how they're using it. That's not usually the case in dermatology. [But] we need to distinguish between antibiotic use that is inappropriate or too long in duration and situations where a patient stays on a drug because it's helping them."

Dr. Lautenbach adds that physician education has been focused on the people who prescribe the most antibiotics. While, as noted above, dermatologists are prescribing more per practice, their total number of prescriptions pale in comparison to outpatient primary care doctors. That same CDC report found dermatologists wrote a total of 7.6 million prescriptions for antibiotics in 2014, while primary care physicians wrote 114.7 million.

"From an education standpoint, there tends to be more value in focusing our efforts on outpatient primary care prescribers," Dr. Lautenbach says in a news release. "Dermatology isn't where we find most use of antibiotics in terms of sheer volume."

FDA Approves Janssen's Tremfya for Moderate To Severe Plaque Psoriasis

The FDA approved Janssen's Tremfya (guselkumab) for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Tremfya is the first and only approved biologic therapy that selectively blocks only IL-23, a cytokine that plays a key role in plaque psoriasis. Approval comes after an expedited regulatory review following application of an FDA Priority Review Voucher.

Tremfya is administered as a 100mg subcutaneous injection every eight weeks, following two starter doses at weeks zero and four. In clinical studies, patients receiving Tremfya experienced significant improvement in skin clearance and greater improvement in symptoms of plaque psoriasis including itch, pain, stinging, burning, and skin tightness when compared with placebo at week 16. Superior results in skin clearance (PASI 90) were demonstrated with Tremfya compared with Humira (adalimumab) at weeks 16, 24, and 48.

"Tremfya represents a significant milestone in the treatment of moderate to severe plaque psoriasis as evidenced by the proven skin clearance demonstrated in the majority of study patients receiving this IL-23–specific therapy at week 16 and up to week 48," said Andrew Blauvelt, MD, MBA, President of Oregon Medical Research Center, and study investigator in a press release. "We continue to make progress in understanding the science of psoriasis and the important role IL-23 plays in the pathogenesis of this disease, which is another reason why today's approval of Tremfya is exciting, both as a researcher and a practicing dermatologist."

Tremfya received FDA approval based on results from a clinical development program that included more than 2,000 patients in the Phase 3 VOYAGE 1, VOYAGE 2, and NAVIGATE studies, which have been published in peer-reviewed journals and were presented at the 25th European

Academy of Dermatology and Venerology Congress and the 2017 American Academy of Dermatology Annual Meeting.

- Results from VOYAGE 1 and VOYAGE 2 demonstrated significant efficacy in patients with moderate to severe plaque psoriasis treated with Tremfya.
- In clinical studies, at 16 weeks, at least seven out of 10 Tremfya-treated patients achieved at least 90 percent clearer skin, and more than 80 percent demonstrated cleared or almost cleared skin.
- Improvements were also demonstrated with Tremfya in psoriasis involving the scalp and in symptoms of plaque psoriasis including itch, pain, stinging, burning, and skin tightness at week 16.
- Treatment with Tremfya resulted in clearer skin that lasted—nearly nine out of 10 Tremfya-treated patients who achieved PASI 90 at week 28 maintained that response at week 48.
- Versus Humira (adalimumab), at week 24, more than seven out of 10 patients treated with Tremfya reported at least 90 percent clearer skin compared with more than four out of 10 patients treated with Humira.
- NAVIGATE findings demonstrated the effectiveness of Tremfya in patients who had an inadequate response to treatment with Stelara (ustekinumab). At week 28, 31 percent of Tremfya-treated patients were considered cleared or almost cleared versus 14 percent of Stelara-treated patients 12 weeks after randomization to continue Stelara or transition to Tremfya.

Janssen says it will work closely with payers, providers, and pharmacy benefit managers to ensure Tremfya is accessible and affordable and that the cost for payers is competitive with currently available biologic therapies for psoriasis. Janssen offers a number of patient support programs, including a co-pay card for patients with commercial insurance that reduces out-of-pocket cost for Tremfya to no more than $5 per dose.

MODERNIZING MEDICINE TO ADD MORE THAN 800 JOBS IN EXPANSION

Modernizing Medicine will expand operations and add a total of 838 jobs by 2022. The expansion, to be implemented in the historic Boca Raton Innovation Center (BRIC) in Palm Beach County will result in a capital investment of more than $15 million in the Boca Raton community.

Florida Governor Rick Scott said, "I am proud that Modernizing Medicine will be expanding in Palm Beach County to create more than 800 new jobs which will provide even more families a great career. Companies like Modernizing Medicine are helping Florida become the best state in the nation for job creation while helping our unemployment rate continue to drop. Now, with the $85 million Florida Job Growth Grant Fund, we will ensure that even more job creators can grow and succeed in Florida."

Headquartered in Boca Raton, Modernizing Medicine was founded in 2010 by chief executive officer Daniel Cane and chief medical and strategy officer Dr. Michael Sherling and has grown to more than 550 employees.

"We are extremely excited to expand our presence and create more jobs across a wide range of fields in South Florida. As a Florida-based technology company, it's not lost on us that we're in the backyard of where the modern day era of technology was born," Mr. Cane said in a statement. "We're proud to work with Enterprise Florida, the City of Boca Raton and the Business Development Board of Palm Beach County to continue to enhance the already stellar reputation as an area of innovation and growth. I look forward to seeing the company's long-term impact on the community as well as the modernization of medicine."

FDA EXPANDS APPROVAL OF YERVOY TO TREAT PEDIATRIC PATIENTS 12 YEARS AND OLDER WITH MELANOMA

The FDA has expanded the indication for Bristol-Myers Squibb's Yervoy (ipilimumab) injection for intravenous use to now include the treatment of unresectable or metastatic melanoma in pediatric patients 12 years of age and older. Yervoy was evaluated in two trials of pediatric patients: a dose-finding study in 33 patients aged two to 21 years with relapsed or refractory solid tumors and an open-label, single-arm trial in 12 adolescents (ages ranging from 12 to 16 years) with previously treated or untreated, unresectable Stage 3 or 4 malignant melanoma. The overall safety profile of Yervoy in children and adolescents was consistent with the safety profile in adults, and similarities in disease between adult and pediatric patients 12 years and older allow for extrapolation of data. Based on a population pharmacokinetic analysis, exposure in adolescents 12 years and older is comparable to that in adults for the approved dose of 3 mg/kg, administered intravenously over 90 minutes every three weeks for a total of four doses.

Yervoy is associated with a Boxed Warning and can result in severe to fatal immune-mediated adverse reactions. These immune-mediated reactions may involve any organ system; however, the most common severe immune-mediated adverse reactions are enterocolitis, hepatitis, dermatitis (including toxic epidermal necrolysis), neuropathy, and endocrinopathy.

This expanded indication for Yervoy marks Bristol-Myers Squibb's first pediatric indication for an immuno-oncology medicine. The expanded indication builds upon six years of experience with Yervoy, which has been used to treat more than 38,000 adult patients with metastatic melanoma since its first approval.

Take 5

WITH BILL HUMPHRIES, EXECUTIVE VICE PRESIDENT AND COMPANY GROUP CHAIRMAN, ORTHO DERMATOLOGICS

Many a pharma industry watcher's antennas went up when news broke that Bill Humphries had left his role as President and CEO of Merz North America, Inc. to serve as Executive Vice President and Company Group Chairman of Valeant's newly minted Ortho Dermatologics division in December 2016. Mr. Humphries resume also boasts turns as President of Dermatology-focused Business at Stiefel and VP of Allergan's US skincare business, so he is uniquely poised to be at the forefront of what he hopes will be the "biggest turnaround in the history of pharmaceuticals."

A TEAM THAT "GETS IT"

"Our relationship with the dermatology community is super important, and the rebranding under Ortho Dermatologics is sending the right message. We have a very seasoned field force that have unrivaled relationships with our customers. Collectively, our management team has more than 100 years of experience in dermatology. This means you have a company for dermatologists being led by people who have experience in dermatology. This is significant because there are some nuances about being in dermatology that most people don't always get. This team gets it."

A FAMILY AFFAIR

"Taking this job is a bit personal and a bit professional. My dad started in the industry at Ortho Dermatologics and this is something that we now bond about. On the professional side, this role gives me the opportunity to work on the biggest turnaround in the history of pharmaceuticals."

UNRIVALLED COLLABORATION

"I find Valeant to be one of the most collaborative places I have ever worked. Our ability to get things done as we look to turn this company around is really exciting. The Ortho Dermatologics rebrand will allow us an opportunity to match words to actions—whether it's how the products are priced, access programs, support for the specialty, charity activities, launching new products to market and the pipeline."

ROBUST, UNDERAPPRECIATED PIPELINE

"Our pipeline is quite robust, and I think it is one of the things that is underappreciated about Ortho Dermatologics because it has been kept a little bit under the radar. We just launched Siliq for the treatment of moderate to severe plaque psoriasis in adult patients. We have publicly discussed IDP-118 (halobetasol propionate and tazarotene) for the treatment of psoriasis, and we believe that this is true innovation, and that patients and physicians will come to appreciate that if it is approved and when we launch. Our pipeline is focused on growing areas in medical dermatology, namely acne, psoriasis, and atopic dermatitis. We now have a portfolio that is tied together with our pipeline and R and D efforts. Physicians and patients can expect an honoring of the legacy that is Ortho Dermatologics, which was a very innovative dermatology company and will be again."

SO FAR, SO GREAT

"Eight months in, and it's going great. Every Friday, I sit back and whether we moved the business a millimeter or 10 yards, I know that we are making progress and that really excites me. The first half of this story is written and I am excited to be part of the team that is actively writing the second half." ■

MEET THE NEW ORTHO DERMATOLOGICS

Valeant's Ortho Derm unit came out of the gate strong and in style at a bash to kick off the Siliq (brodalumab) launch and the name change, during the Summer AAD meeting in New York City.

The fete, which was held on the top of the swanky Sanctuary Hotel as the new logo danced across the rooftops of surrounding buildings, also kicked off "1:1 Connections," a customer-focused campaign that highlights the senior team's experience and passion for dermatology.

"The dermatology business is an integral part of Valeant's overall business strategy, and we are investing resources for continued success rebuilding derm leadership team and supporting key brands," said Valeant CEO and Chairman Joseph C. Papa at the event.