



Dealing With Non-Compliant Patients: Avoiding Liability

The first step in avoiding liability due to patient non-compliance is identifying that the patient actually is non-compliant. Then, ask about the reason for it and do what you can to counter it. Your record must reflect your attempt to determine what correctable issues underlie the non-compliance and what steps you took to counter it. If non-compliance is not solvable as a single issue and verbal reminders are not fruitful, you can consider a treatment contract, which breaks the compliance into specific acts of patient cooperation that may be easier to follow. Your last option is an "at risk" letter that states the specific non-compliant acts and their clinical consequences. This can include the warning that a failure to correct the non-compliance will result in termination from the practice. You should not create a "decline" note in which the patient signs their refusal to comply. You would be retaining the patient in your practice despite being unable to treat them as you believe is proper.

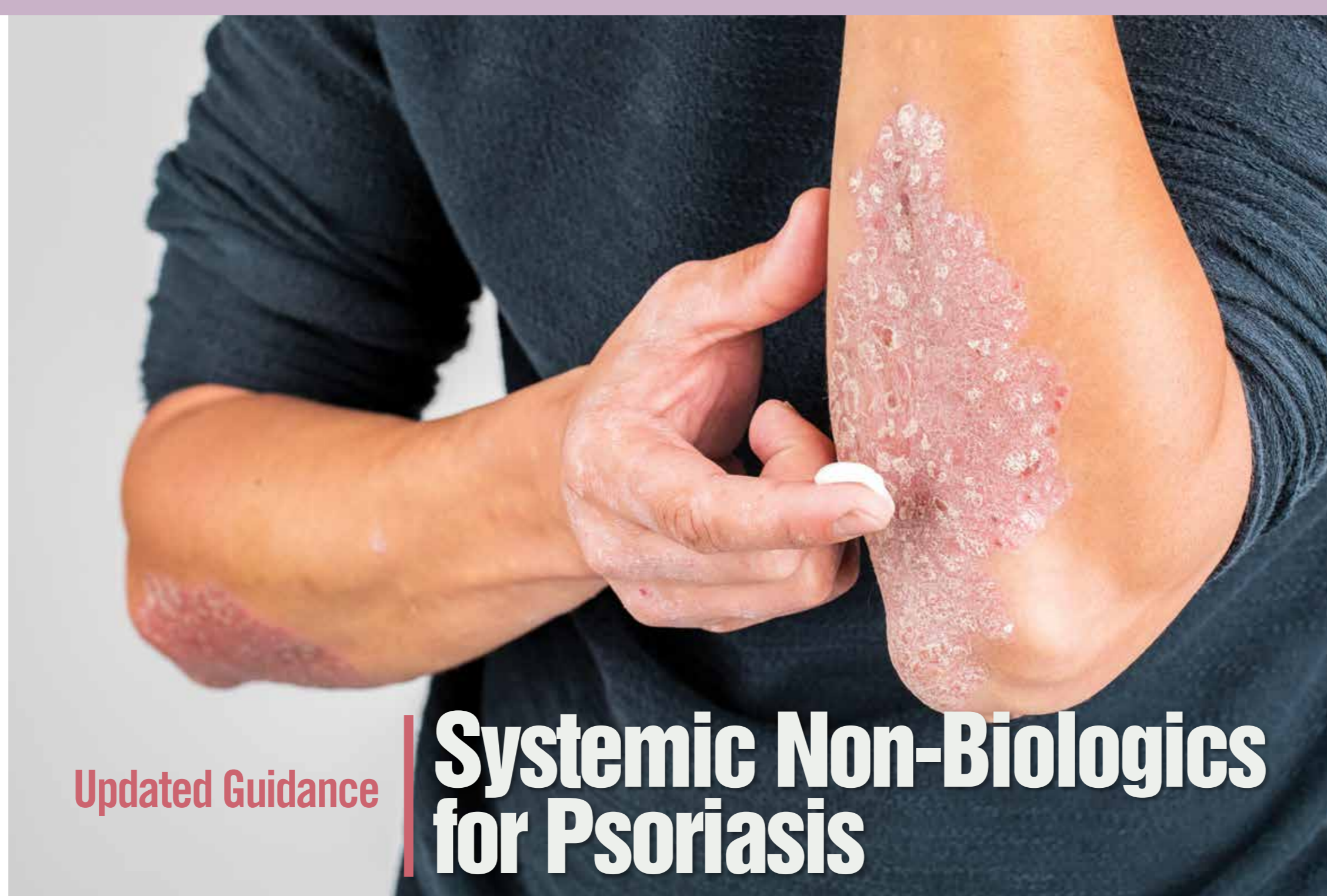
Your records need to demonstrate that the patient is being non-compliant rather than just being ill-informed. Descriptions of the patient's non-compliant conduct should state the fact of the non-compliance undeniably but without condemnatory or self-serving language. But it should not be so removed as to become meaningless in convincing a reviewer that you are not an appropriate target or in closing off patient claims that you never said something you actually did.

When the therapeutic relationship is irrevocably broken down and it is necessary for you to step away because the patient is actually preventing you from practicing medicine properly, you will have to terminate them from your practice. You will then have to consider abandonment. If you are going to take the maximum step against someone who is already in opposition to you, do so carefully. Non-compliance leading to no option but termination is a gradual process by definition and so an evaluator will want to see that it was handled that way.

You should also consider stating the reason for the termination in a letter. The general rule is to not give a specific reason, but here stating "As we have discussed, and as outlined in the treatment contract that you agreed to, it was essential that you follow through on prescribed care. Due to your continued refusal to follow treatment guidelines, this practice will no longer be able to retain you as a patient as of (date)" may stop a retaliatory process before it starts.

This article was written by Dr. Medlaw, a physician and medical malpractice attorney.

LIABILITY



Updated Guidance | Systemic Non-Biologics for Psoriasis



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Better & Safer Outcomes

To provide clinicians and other stakeholders with comprehensive, evidence-based recommendations for the use of systemic non-biologic treatments for psoriasis so that patients can achieve better and safer outcomes, Dr. Gelfand and colleagues developed updated guidelines of care, published in the *Journal of the American Academy of Dermatology*, for the management of psoriasis with systemic non-biologic therapies (Table).

"The biggest change with the new guidelines is that they deemphasize the use of liver biopsy and emphasize the use of new non-invasive blood tests and imaging (specialized ultrasound or MRI) to detect signs of liver damage from methotrexate," says Dr. Gelfand. "With advances in testing that can detect liver fibrosis at an early stage, most patients can be treated safely with methotrexate—a treatment used for over 50 years for psoriasis—without the need for a liver biopsy, as was recommended in the past. This advance will come as a great relief to our patients and clinicians and demonstrates that progress is made not only with new treatments, but also in improving older therapies."

Although less focus is given to the other FDA-approved medications for psoriasis, the guidelines do recommend apremilast for the treatment of moderate to severe psoriasis in adults, with benefits

that include oral administration and the lack of a requirement for laboratory monitoring and disadvantages that include slower onset of skin clearance and lower likelihood of clearing when compared with injectable agents. The guidelines also recommend cyclosporine for patients with severe, recalcitrant psoriasis, adding that the drug can be recommended for the treatment of erythrodermic, generalized pustular, and/or palmoplantar psoriasis as well as for short-term interventional therapy in patients who flare up while on a pre-existing systemic therapy. Lastly, the guidelines state that

acitretin can be recommended as monotherapy for plaque psoriasis; treatment of erythrodermic, pustular, and palmoplantar psoriasis; combination therapy with psoralens with ultraviolet A for psoriasis; and combined with broadband ultraviolet B for plaque psoriasis.

In regard to why several non-FDA-approved medications are covered in the guidelines, Dr. Gelfand notes that while tofacitinib, for example, is not approved by the FDA as a treatment of psoriasis, large randomized, placebo-controlled trials indicate that it is efficacious in the treatment of skin disease. "It is FDA-approved for psoriatic arthritis, so it is important that dermatologists are aware of the role this drug has to play in the management of psoriatic disease," he adds. "We also touch on the use of fumarates, which are used for psoriasis in Europe. While they are not approved for psoriasis in the US, they are approved for the treatment of multiple sclerosis (MS) and thus may have a role to play in patients living with both diseases. For example, we cannot use TNF alpha inhibitors in patients with MS, as it can make MS worse, so a treatment that can improve both conditions may be a good option for some patients."

Looking Ahead

Dr. Gelfand notes that advances in oral medications have lagged behind those in injectable biologic medicines for the common and incurable condition that is psoriasis. "Many patients prefer a pill over an injection, and therefore, we have a significant unmet need for oral medications for psoriasis that are highly effective and well tolerated," he adds. "There is also a need for 'personalized medicine,' in which we can advise patients on the best drug for them based on their genetics, health status, and preferences."

In the meantime, Dr. Gelfand stresses the transformative changes in recommendations for monitoring liver damage from methotrexate in the guidelines. "Physicians should rapidly adopt these new recommendations so patients can be spared the pain, anxiety, cost, and inconvenience that comes with a liver biopsy and instead have monitoring with simple blood tests and imaging techniques that can detect liver damage long before it becomes clinically significant," he says.

Table Oral Systemic Non-Biological Therapies

The table shows the agents covered in the joint AAD-NPF Guidelines of Care for the Management of Psoriasis With Systemic Non-Biological Therapies. The writing committee addressed the efficacy, effectiveness, adverse effects, contraindications, and recommended monitoring for each in the treatment of adults with psoriasis.

Therapy	FDA Approval to Treat Psoriasis
Methotrexate	1972
Apremilast	2014
Cyclosporine	1997
Acitretin	1997
Tofacitinib	Not FDA approved for psoriasis
Fumaric acid esters	Not FDA approved for psoriasis
Hydroxyurea	Not FDA approved for psoriasis
Mycophenolate mofetil	Not FDA approved for psoriasis
Azathioprine	Not FDA approved for psoriasis
Leflunomide	Not FDA approved for psoriasis
Tacrolimus	Not FDA approved for psoriasis
Thioguanine	Not FDA approved for psoriasis

Source: Adapted from: Menter A, et al. *J Am Acad Dermatol*. 2020;82:1445-1486.

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Is There Life After Medicine?

By Brian Rifkin, MD

My group of nephrologists is trying to convince our 75-year-old colleague to retire from full-time clinical practice. I think he truly believes that the day he retires, his essence will be forcibly removed from his body, and he will cease to exist. He has told me, more than once, that he will be dead in less than a year if he is forced to stop being a physician. I envisioned this type of machismo was very old-school thinking, but maybe not. Modern doctors strive for a better balance of work and life, but do you ever really stop being a physician?

We all have many titles in life. What happens when the title remains, but the interactions cease? I strive to add quality and not just quantity to the lives of my patients who need to start dialysis. I have type 1 diabetes and realize that their reality may someday be mine. I hope to retire young enough that I can still enjoy all life has to offer.

In nephrology, where we have not been filling fellowship training spots, we are failing to replace ourselves in the workforce. There will likely be a need for me to prolong my work life. When I think about stopping my medical practice, I think about the million ways to not do medicine: volunteering, teaching, reading, writing, relaxing. I love interacting and helping patients. I do not, however, always enjoy the structural, administrative, and financial barriers imposed by day-to-day practice. This has been my point to my senior partner; why not take the best parts of medicine and only do those things that add meaning and pleasure to your life?

But is my partner correct? Do we lose something when we retire? There is some evidence that waiting to retire may have some health benefits. In a 2019 Swedish study, it was suggested that working past age 65 was associated with better overall health, but one can certainly argue cause and effect in this type of observation. Not debatable is that the average age of American physicians is increasing. In a 2017 survey by CompHealth, doctors reported an average retirement age of 68 (vs 63 for all Americans), and only 32% said they looked forward to no longer working in medicine. Losing social interactions at work, feeling a loss of purpose, boredom, loneliness, and depression may provoke an identity crisis at the end of a physician's career.

The ideal retirement means something different for every physician. However, it is clear that the valuable skills we acquire afford the opportunity to contribute long into our golden years. I hope that when I am 75, I have the choice to contribute (or not) as I see fit. There is purpose in being a doctor. The trap is when you assume all that you are is a doctor.

Brian Rifkin, MD, is a nephrologist.

In Case You Missed It



Adverse Pregnancy Outcomes Up for Women With Psoriasis

Pregnancies in women with psoriasis have an increased risk for adverse outcomes, including preeclampsia and stillbirth, according to a study published in the *Journal of Dermatology*. Researchers examined maternal and fetal outcomes for mothers with psoriasis using a population-based nationwide health registrar database. A total of 2.35 million singleton pregnancies were identified from 2001 to 2012, including 4,058 singleton pregnancies among patients with psoriasis. The adjusted odds ratios (95% confidence intervals [CIs]) were 1.57 (1.31 to 1.89), 1.50 (1.28 to 1.75), and 1.57 (1.36 to 1.82) for preeclampsia, pregnancy-related hypertension, and severe postpartum hemorrhage, respectively, for pregnancies among patients with psoriasis. The adjusted odds ratios (95% CIs) were 1.48 (1.11 to 1.96), 1.27 (1.14 to 1.41), 1.13 (1.02 to 1.25), 1.12 (1.02 to 1.23), and 1.09 (0.96 to 1.25) for stillbirth, low birthweight of less than 2,500 g, preterm labor, small for gestational age, and fetal distress, respectively, among offspring of women with psoriasis. Babies born to mothers with psoriasis also had lower Apgar scores. "We found in this study that pregnancies in women with psoriasis were at higher risk of adverse pregnancy outcomes, including stillbirth and postpartum hemorrhage," the authors write. "However, despite a high [relative] risk, most pregnancies are successful."

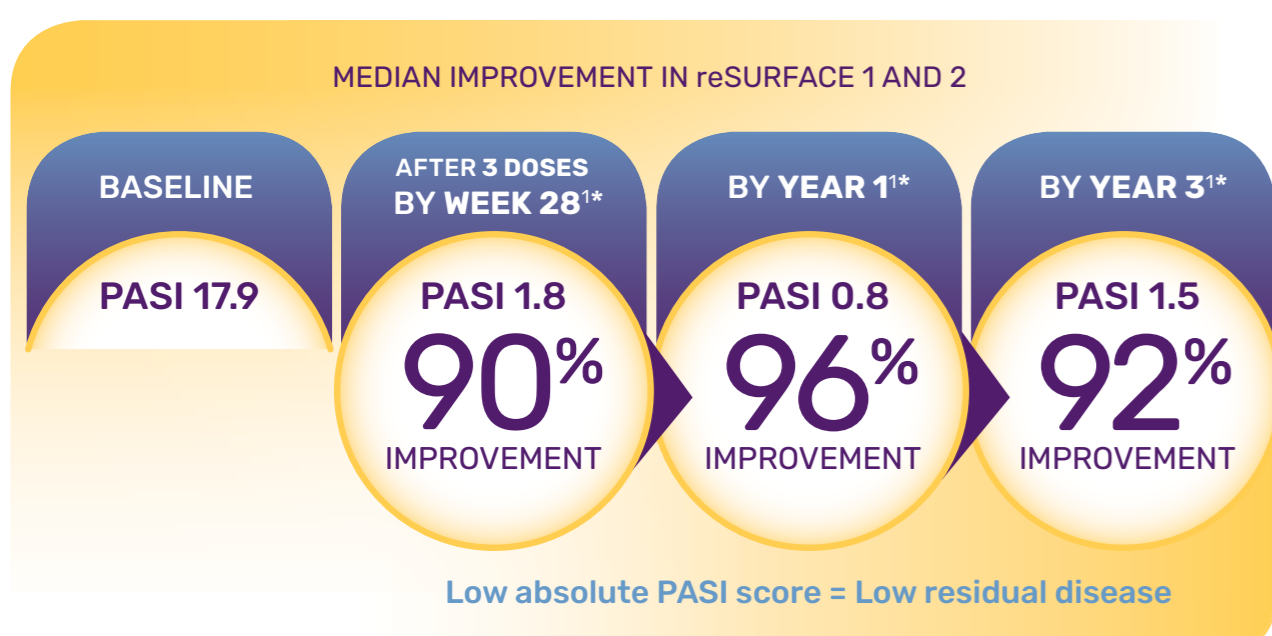
Antidepressants Protect Against Psoriasis Risk in Patients With Major Depressive Disorder

Study results appear to reveal the protective effects of antidepressants on psoriasis risk in patients with major depressive disorder (MDD), according to a paper published in the *Journal of Affective Disorders*. With prior research suggesting that inflammation may mediate the relationship between MDD and psoriasis but it remaining unclear whether antidepressants can decrease the subsequent risk of psoriasis among patients with MDD, investigators assessed this potential relationship among patients with MDD who were grouped into those who had, or had not, received antidepressants. Participants were tracked for a diagnosis of psoriasis over 5 years. Upon time-dependent Cox regression with both inverse probability of treatment weighting (IPTW) and adjustment for confounders, the study team found that antidepressant users had a significantly lower risk of psoriasis than nonusers (IPTW-adjusted hazard ratio [aHR], 0.69), with most types and dosages of antidepressants tending to protect against psoriasis. Even following IPTW and adjustment for confounders, selective serotonin reuptake inhibitor use (IPTW-aHR, 0.67) and low-dose antidepressant use (IPTW-aHR, 0.66) had significant protective effects.

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Median PASI Score Rapidly Reduced and Sustained Through Year 3¹



At Week 28, responders were re-randomized to 100 mg, 200 mg, or treatment withdrawal, and non-responders (14.4%) were discontinued from therapy. Data represents recommended 100 mg group.^{1,2}

Co-primary endpoints:
PGA 0/1 with at least a 2-point improvement, and PASI 75, both at Week 12³
▶ After 2 doses, by Week 12, 58% (reSURFACE 1) and 55% (reSURFACE 2) achieved PGA 0/1 vs placebo: 7% and 4% (reSURFACE 1 and reSURFACE 2, respectively)
▶ After 2 doses, by Week 12, 64% (reSURFACE 1) and 61% (reSURFACE 2) achieved PASI 75 vs placebo: 6% and 6% (reSURFACE 1 and reSURFACE 2, respectively)

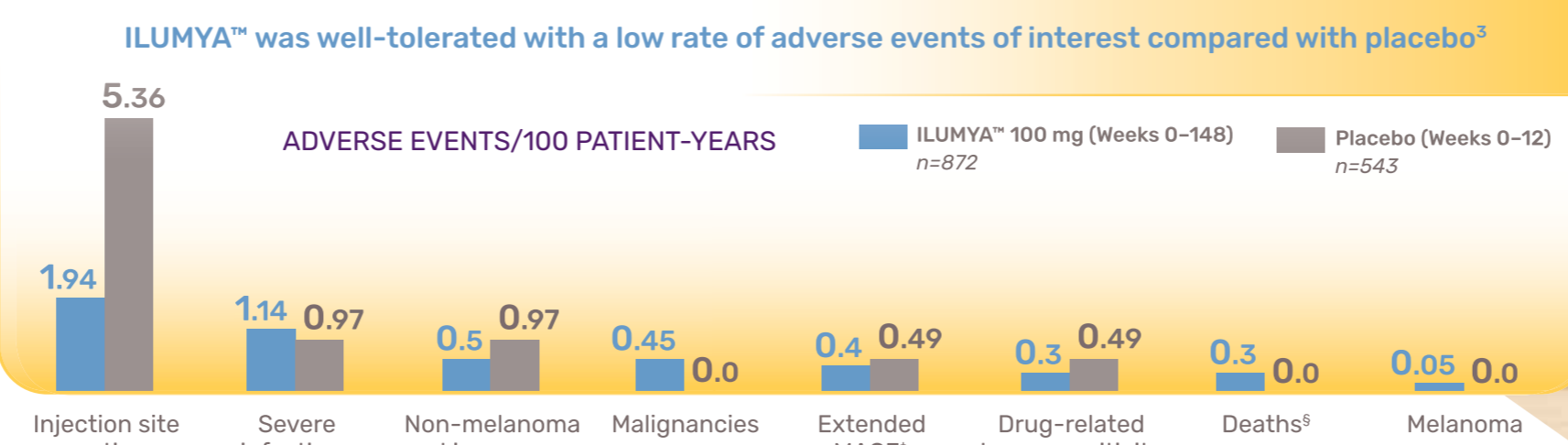
¹From a pooled analysis of reSURFACE 1 and 2. Conducted with non-responder imputation.
²From a post hoc pooled-analysis extension study of reSURFACE 1 and 2.
³Extended MAE includes non-fatal myocardial infarction, non-fatal stroke, unstable angina, coronary revascularization, resuscitated cardiac arrest, and CV deaths that are confirmed as "cardiovascular" or "sudden."
⁴Five subjects in the ILMUYA™ 100 mg group experienced non-treatment-related fatal AEs.
⁵MAE=Major adverse cardiovascular events; PASI=Psoriasis Area and Severity Index; PGA=Physician Global Assessment.

INDICATION
ILUMYA™ (tildrakizumab-asmn) is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

IMPORTANT SAFETY INFORMATION
CONTRAINDICATIONS
ILUMYA™ is contraindicated in patients with a previous serious hypersensitivity reaction to tildrakizumab or to any of the excipients.

WARNINGS AND PRECAUTIONS
Hypersensitivity
Cases of angioedema and urticaria occurred in ILMUYA™-treated subjects in clinical trials. If a serious allergic reaction occurs, discontinue ILMUYA™ immediately and initiate appropriate therapy.

DEMONSTRATED SAFETY OVER 3 YEARS^{3†}



Infections
ILUMYA™ may increase the risk of infection. Treatment with ILMUYA™ should not be initiated in patients with a clinically important active infection until the infection resolves or is adequately treated.

Consider the risks and benefits of treatment prior to prescribing ILMUYA™ in patients with a chronic infection or a history of recurrent infection. Instruct patients receiving ILMUYA™ to seek medical help if signs or symptoms of clinically important chronic or acute infection occur. If a patient develops a clinically important or serious infection, or is not responding to standard therapy, closely monitor and consider discontinuation of ILMUYA™ until the infection resolves.

Pretreatment Evaluation for Tuberculosis
Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with ILMUYA™. Do not administer ILMUYA™ to patients with active TB infection. Initiate treatment of latent TB prior to administering ILMUYA™. Consider anti-TB therapy prior to initiation of ILMUYA™ in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Patients receiving ILMUYA™ should be monitored closely for signs and symptoms of active TB during and after treatment.

Immunizations
Prior to initiating therapy with ILMUYA™, consider completion of all age-appropriate immunizations according to current immunization guidelines. Patients treated with ILMUYA™ should not receive live vaccines.

Adverse Reactions
The most common (≥1%) adverse reactions associated with ILMUYA™ treatment that were more frequent than in the placebo group are upper respiratory infections, injection-site reactions, and diarrhea.

Please see Full Prescribing Information in pocket.

reSURFACE 1 (N=463) and reSURFACE 2 (N=463) were Phase 3, double-blind, placebo-controlled trials of ILMUYA™ given at Weeks 0, 4, and every 12 weeks thereafter. Patients with moderate-to-severe plaque psoriasis who were candidates for phototherapy or systemic therapy were randomized to ILMUYA™ 100 mg or placebo.^{1†}

References: 1. Data on File, Sun Pharmaceutical Industries, Inc. 2. ILMUYA™ (package insert). Princeton, NJ: Sun Pharmaceutical Industries, Inc. 3. Thaçi D, Herren L, Pflüger C, et al. Long-term efficacy and safety of tildrakizumab in patients with moderate-to-severe psoriasis who were responders at week 28: pooled analysis through 3 years (148 weeks) from reSURFACE 1 and reSURFACE 2 phase 3 trials. Paper presented at: 27th Congress of the European Academy of Dermatology and Venereology (EADV), September 12-16, 2018, Paris, France. ILMUYA™ is a trademark of Sun Pharma Global FZE. © 2020 SUN Dermatology, a division of Sun Pharmaceutical Industries, Inc. All rights reserved. PM-US-ILY-1074 Q3/2020

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