SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	CANADA			1978	44 Years	Female	Unk		JUN	2022

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)

Other Serious Criteria: Medically Significant
her skin is very sensitive [Sensitive skin]
secondary diagnosis of HS/ MD was concerned about the on-going Hidradenitis Suppurativa abscesses that are forming [Drug ineffective]
primary diagnosis as Plaque Psoriasis/ Physician has sent a new prescription with 160 mg week 0, 80 mg week 2 followed by 40 mg weekly starting week 4 [Off label use]
primary diagnosis as Plaque Psoriasis/ Physician has sent a new prescription with 160 mg week 0, 80 mg week 2 followed by 40 mg weekly starting week 4 [Off label use]

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Abrilada (ADALIMUMAB) Solution for injection in pre-filled pen

(Continued on Additional Information Page)

15. DAILY DOSE(S)
#1) week 0 dose (Continued on Additional Information Page)

16. ROUTE(S) OF ADMINISTRATION
#1) Subcutaneous

17. INDICATION(S) FOR USE
#1) Plaque Psoriasis (Psoriasis)

(Continued on Additional Information Page)

18. THERAPY DATES(from/to)
#1) 15-JUN-2022 / 15-JUN-2022

19. THERAPY DURATION
#1) 1 day

20. DID REACTION ABATE AFTER STOPPING DRUG?
☐ YES ☐ NO ☒ NA

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
☐ YES ☐ NO ☒ NA

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) BENZALKONIUM (BENZALKONIUM) ; Ongoing
#2) BIMEKIZUMAB (BIMEKIZUMAB) ; Ongoing
#3) CYCLOSPORINE (CICLOSPORIN) ; Ongoing

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
Unknown	Relevant Med History secondary diagnosis	Hidradenitis suppurativa (Hidradenitis)
Unknown	Relevant Med History Primary diagnosis	Plaque psoriasis (Psoriasis)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Pfizer Inc
Head Drug Safety Surveillance
219 East 42nd Street
New York, New York 10017 UNITED STATES
Phone: 212 733 5544

26. REMARKS

24b. MFR CONTROL NO.
202200902755

24c. DATE RECEIVED BY MANUFACTURER
05-AUG-2022

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☒ OTHER: Spontaneous

DATE OF THIS REPORT
10-AUG-2022

25a. REPORT TYPE
☐ INITIAL ☐ FOLLOWUP:

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

little dots on thighs [Petechiae]
Large rashes are seen on first two injection sites and a smaller rash on the last one [Injection site rash]
two new abscesses/recent infection abscess [Abscess bacterial]
Reddened, raised areas at Abrilada injection sites/redness [Injection site erythema]
she has formed reddened, raised areas which she identifies as the Abrilada injection sites. They itch/burn when she scratches them. [Injection site pruritus]
she has formed reddened, raised areas which she identifies as the Abrilada injection sites. They itch/burn when she scratches them. [Injection site pain]
she broke out in a rash (upper leg, mid section, chest and arms) since 29Jul2022 [Rash]

Case Description: This is a spontaneous report received from contactable reporter(s) (Consumer or other non HCP, Physician, Other HCP and Pharmacist), Program ID: (172660).

A 44-year-old female patient received adalimumab (ABRILADA), first regimen from 15Jun2022 (Batch/Lot number: unknown) to 15Jun2022 at 80 mg (week 0 dose, then 40 mg every other week), second regimen from 15Jun2022 (Batch/Lot number: unknown) to 15Jun2022 at 80 mg (80 mg, week 0 dose prefilled pen), third regimen since 23Jun2022 (Batch/Lot number: unknown) at 1 DF (1 df, week 0 80mg, then 40 mg every other week) and fourth regimen since 23Jun2022 (ongoing) (Batch/Lot number: unknown) at 1 DF (1 df (week 0 160 mg, week 2 - 80mg, then 40 mg every week starting week 4 - prefilled pen)), all subcutaneous for psoriasis, hidradenitis. The patient's relevant medical history included: "HS" (unspecified if ongoing), notes: secondary diagnosis; "Plaque Psoriasis" (unspecified if ongoing), notes: Primary diagnosis. Concomitant medication(s) included: CYCLOSPORINE (ongoing); BENZALKONIUM (ongoing). Past drug history included: Bimekizumab, reaction(s): "Adverse reaction", notes: Adverse reaction to bimekizumab (Bimzelx, anti-IL17A, anti-IL-17F, and anti-IL17AF monoclonal antibody).
The following information was reported: INJECTION SITE RASH (non-serious) with onset Jun2022, outcome "unknown", described as "Large rashes are seen on first two injection sites and a smaller rash on the last one"; INJECTION SITE ERYTHEMA (non-serious) with onset Jun2022, outcome "not recovered", described as "Reddened, raised areas at Abrilada injection sites/redness"; INJECTION SITE PRURITUS (non-serious), INJECTION SITE PAIN (non-serious) all with onset Jun2022, outcome "not recovered" and all described as "she has formed reddened, raised areas which she identifies as the Abrilada injection sites. They itch/burn when she scratches them."; ABSCESS BACTERIAL (non-serious) with onset Jun2022, outcome "unknown", described as "two new abscesses/recent infection abscess"; PETECHIAE (non-serious) with onset 24Jun2022, outcome "unknown", described as "little dots on thighs"; DRUG INEFFECTIVE (non-serious), outcome "unknown", described as "secondary diagnosis of HS/ MD was concerned about the on-going Hidradenitis Suppurativa abscesses that are forming"; OFF LABEL USE (non-serious), OFF LABEL USE (non-serious), outcome "unknown" and all described as "primary diagnosis as Plaque Psoriasis/ Physician has sent a new prescription with 160 mg week 0, 80 mg week 2 followed by 40 mg weekly starting week 4". The action taken for adalimumab was dosage not changed. Therapeutic measures were taken as a result of abscess bacterial.
Additional information: Patient received second dose on 23Jun2022 and noticed little dots on thighs on 24Jun2022. It got worse over the weekend. Large rashes are seen on first two injection sites and a smaller rash on the last one. Patient stated that her psoriasis is 'beautiful' she's not had skin like this at her breast/armpit area in over 20 years. Smooth, brown/healing, no signs of redness. As previously known, she has a secondary diagnosis of HS. She unfortunately also reports two new abscesses, one in intergluteal fold (described as big and hard) and one on her left buttock (scabbed). Patient was seen in Urgent Care this weekend for her neck abscesses/pain. In Urgent Care, she was prescribed Keflex 500mg TID the first time and offered/took written Rx for Doxy 100mg BID. She started the Keflex but isn't sure if she should start the doxy (and the urgent care MD also wasn't sure). Additionally, she has formed reddened, raised areas which she identifies as the Abrilada injection sites. They itch/burn when she scratches them. Those appeared this weekend, 3-4 days after her second Abrilada dose on 22Jun2022. On 28Jun2022, Physician called in to discuss the medical clarification (query injection site reaction): MD was not concerned with the redness as it was a common side effect. MD was concerned about the on-going Hidradenitis Suppurativa abscesses that are forming. She wanted to re-induce patient at a Hidradenitis Suppurativa dose level and then HS dose maintenance (off label use) but keeping primary diagnosis as Plaque Psoriasis. Physician has sent a new prescription with 160 mg week 0, 80 mg week 2 followed by 40 mg weekly starting week 4, it was reported "Abrilada: 1 DF, Week 0 160 mg, week 2 - 80mg, then 40 mg every week starting week 4 - not started yet". On 05Jul2022, the pharmacist reported that the patient experienced a recent infection abscess for which she had to take antibiotics. She also had a bit of redness at the injection site. As of 29Jul2022, the patient stated her HS has been worse, had 6-7 incidents since starting, had not had any for a while. Hoping now that she is through the loading phase and on weekly injections it calms down.

The information on the batch/lot number for adalimumab has been requested and will be submitted if and when received.

Follow-up (28Jun2022 and 28Jun2022): These are follow-up spontaneous reports from contactable reporter(s) (Physician), Program ID: (172660). Updated information included: the patient's medical history (added Plaque Psoriasis), suspect drug data (added indication of "Hidradenitis Suppurativa"), reaction data (event details for "Injection side redness", added new events of "Drug ineffective, Off label dosing amount and Off label dosing frequency").

No follow-up attempts are needed; information about lot/batch number cannot be obtained. No further information is expected.

Follow-up (05Jul2022): This is a follow-up spontaneous report from a contactable pharmacist. Updated information: course of events ("recent infection abscess for which she had to take antibiotics").

Mfr. Control Number: 202200902755

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The information on the batch/lot number for adalimumab has been requested and will be submitted if and when received.

Follow-up (12Jul2022): Follow-up attempts are completed. No further information is expected.

Follow-up (29Jul2022): This is a follow-up spontaneous report from a Pfizer-sponsored program [172660] received from a contactable Physician (consumer).
Updated information includes: past drug history and clinical course details.

No follow-up attempts are needed. No further information is expected.

Follow-up (05Aug2022) This is a follow-up spontaneous report from a Pfizer sponsored program (172660) received from a contactable Consumer.

Updated information included:
Concomitant medication Bimekizumab was added.
New event of "Sensitive skin (Medically significant)", Outcome: Unknown
New event of "Rash", Outcome: Not recovered/Not resolved, Onset date: 29Jul2022

Additional information:
Patient sent an email to the program stating that she broke out in a rash (upper leg, mid section, chest and arms) since 29Jul2022, her skin is very sensitive and the rash is still present. Patient asked if this could be related to the Abrilada.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Abrilada (ADALIMUMAB) Solution for injection in pre-filled pen; Regimen #1	week 0 dose, then 40 mg every other week; Subcutaneous	Plaque Psoriasis (Psoriasis) Hidradenitis Suppurativa (Hidradenitis)	15-JUN-2022 / 15-JUN-2022; 1 day
#1) Abrilada (ADALIMUMAB) Solution for injection in pre-filled pen; Regimen #2	80 mg, week 0 dose Prefilled pen; Subcutaneous	Plaque Psoriasis (Psoriasis) Hidradenitis Suppurativa (Hidradenitis)	15-JUN-2022 / 15-JUN-2022; 1 day
#1) Abrilada (ADALIMUMAB) Solution for injection in pre-filled pen; Regimen #3	1 DF, Week 0 80mg, then 40 mg every other week; Subcutaneous	Plaque Psoriasis (Psoriasis) Hidradenitis Suppurativa (Hidradenitis)	23-JUN-2022 / Unknown; Unknown
#1) Abrilada (ADALIMUMAB) Solution for injection in pre-filled pen; Regimen #4	1 DF (Week 0 160 mg, week 2 - 80mg, then 40 mg every week starting week 4 - Prefilled pen); Subcutaneous	Plaque Psoriasis (Psoriasis) Hidradenitis Suppurativa (Hidradenitis)	23-JUN-2022 / Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Past Drug Event	bimekizumab (BIMEKIZUMAB); Drug Reaction: Adverse reaction (Adverse reaction)
	Adverse reaction to bimekizumab (Bimzelx, anti-IL17A, anti-IL-17F, and anti-IL17AF monoclonal antibody)	