Sciegen Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of Irbesartan Tablets

[October 26 & October 30, 2018]

To date 2 alerts have been received by: Sciegen Pharmaceuticals and Aurobindo Pharma limited. Below you will find information on the alerts based on the manufacturer.

ScieGen Pharmaceuticals, Inc. is voluntarily recalling listed lots, within expiry, of Irbesartan Tablets, USP 75 mg, 150 mg, and 300 mg dosage forms to the consumer level. These products are being recalled due to the presence of an impurity, N-nitrosodiethylamine (NDEA) contained in the API Irbesartan, USP manufactured by Aurobindo Pharma Limited. This impurity, which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC)

To date, Sciegen Pharmaceuticals Inc has not received any reports of adverse events related to this product.

Irbesartan tablets, USP are indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

Irbesartan Tablets, USP 75 mg, 150 mg, and 300 mg were manufactured by ScieGen Pharmaceuticals Inc and are labeled as Westminster Pharmaceuticals and Golden State Medical Supply, Inc [GSMS].

The recalls and returns will be managed by the respective distributors separately for the lots distributed by them as outlined below.

Details of batches sent to **Westminster**

The Irbesartan tablets subject to recall are packed in 30-count and 90-count bottles. To help identify the recalled product, the NDCs, product description, lot numbers and expiration dates are listed below. These lots were distributed nationwide in the USA to Westminster's direct accounts.

NDC #	Product Description	Lot#	Expiration Date
69867-0119-01	Irbesartan 75mg Tablets, 30 count bottle	B160002A	Sep-19
69867-0119-03	Irbesartan 75mg Tablets, 90 count bottle	B160002B	Sep-19
69867-0120-01	Irbesartan 150mg Tablets, 30 count bottle	B161005A	Sep-19
		C161002A	Feb-20
69867-0120-03	Irbesartan 150mg Tablets, 90 count bottle	B161005B	Sep-19
		C161002B	Feb-20
69867-0121-01	Irbesartan 300mg Tablets, 30 count bottle	B162008A	Sep-19
		C162002A	Feb-20
69867-0121-03	Irbesartan 300mg Tablets, 90 count bottle	B162008B	Sep-19
		C162002B	Feb-20

Westminster is notifying its direct accounts by email and by phone to immediately discontinue distribution of the product being recalled and to notify their wholesale and retail accounts of this product recall and make arrangements for impacted product to be returned to Westminster. Instructions for returning recalled products are provided in the Recall Notice Letter and Recall Response Form. Patients should return the effected medication to their pharmacy. Pharmacies should return their effected stock to their wholesaler.

If you are taking Irbesartan, please examine your tablets and look for the specific markings to determine if you're product is affected by this recall. Products can be best identified by patients as being white, oval shaped tablets debossed with SG 160; SG 161; or SG 162.

Customers and patients with medical-related questions, information about an adverse event or other questions about the Westminster's product's being recalled should contact Westminster's Regulatory Affairs department by phone at: 888-354-9939

Live calls are received Monday-Friday, 9:00AM - 5:00PM EST with voicemail available 24 hours/day, 7 days/week or email recalls@wprx.com.

Details of batches sent to **Golden State Medical Supply, Inc [GSMS]**

The products subject to recall are packed in 30-count and 90-count bottles. To help identify the recalled product, the NDCs, Product Description, Lot numbers and Expiration dates are listed below. These lots were distributed nationwide in the USA to GSMS' direct accounts.

NDC #	Product Description	Lot#	Expiration Date
60429-0641-30	Irbesartan 150mg Tablets, 30 Count Bottle	GS019526	Nov-19
		GS020252	Nov-19
		GS020958	Nov-19
60429-0642-30	Irbesartan 300mg Tablets, 30 Count Bottle	GS019036	Sep-19
		GS019073	Sep-19
		GS021472	Nov-19
		GS021530	Nov-19
		GS022234	Feb-20
60429-0640-90	Irbesartan 75mg Tablets, 90 Count Bottle	B160003	Sep-19
		B160004	Sep-19
60429-0641-90	Irbesartan 150mg Tablets, 90 Count Bottle	B161003	Sep-19
		B161004	Sep-19
		B161006	Sep-19
		B161007	Sep-19
		B161008	Nov-19
		B161009	Nov-19
		B161010	Nov-19
		C161001	Feb-20
		C161003	May-20
60429-0642-90	Irbesartan 300mg Tablets, 90 Count Bottle	B162009	Sep-19
		B162010	Sep-19
		B162011	Sep-19
		B162012	Nov-19
		B162013	Nov-19
		B162014	Nov-19
		B162015	Nov-19
		C162001	Feb-20

Complete the Recall Inventory Response Form and return to Golden State Medical Supply Incorporated email: recalls@gsms.us or by via Fax: (805) 477-9869 Contact Golden State Medical Supply Incorporated for directions on return authorizations by calling (800) 284-8633 ext. 215 between 7:30AM-4:00PM Pacific; or email: recalls@gsms.us.

If you are taking Irbesartan, please examine your tablets and look for the specific markings to determine if you're product is affected by this recall. Products can be best identified by patients as being white, oval shaped tablets debossed with SG 160; SG 161; or SG 162.

Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication. Patients who are on Irbesartan should continue taking their medication, as the risk of harm to a patient's health may be higher if the treatment is stopped immediately without any alternative treatment. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using Irbesartan.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

• Complete and submit the report Online: www.fda.gov/medwatch/report.htm

• **Regular Mail or Fax**: Download form www.fda.gov/medwatch/report.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being made with the knowledge of the Food and Drug Administration.

Click here to Access FDA Alert

Aurobindo Pharma Limited

Aurobindo Pharma Limited is voluntarily recalling 22 Batches of the drug substance Irbesartan due to the presence of an impurity, N-nitrosodiethylamine (NDEA). The impurity, which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC).

These 22 batches of Irbesartan drug substance were supplied to ScieGen Pharmaceuticals Inc., U.S. for the manufacturing of finished Irbesartan drug product (see attached annexure).

Aurobindo Pharma Limited has notified ScieGen Pharmaceuticals, Inc. of the recall and is arranging for the return of all available Irbesartan drug substance. Aurobindo Pharma Limited has further advised Sciegen Pharmaceuticals, Inc. to contact its distributors and retailers to return Irbesartan drug product and finished Irbesartan tablets that has been identified by Aurobindo Pharma Limited.

Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication. Patients who are on Irbesartan should continue taking their medication, as the risk of harm to a patient's health may be higher if the treatment is stopped immediately without any alternative

treatment. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using Irbesartan.

Adverse reactions or quality problems associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

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Annexure -I
Irbesartan batches Supplied to US Customers

No	Manufacturing Batch Number	Dispatch Batch Number	Date of Manufacture	Date of Distribution	Retest/Expiry Date	Dispatch Qty	Name and Location of the Customer	NDEA Impurity Result ug/g
1	1601100782	1601101589	Jan-16	Jan-16	Dec-16	90.29 Kg	Sciegen Pharmaceuticals INC, USA	0.23
2	1601100783	1601101590	Jan-16	31-Jan-16	Dec-16	59.61 Kg	Sciegen Pharmaceuticals INC, USA	0.28
3	1701111861	1701113404	13-Sep-17	7-Oct-2017	12-Sep-20	88.48 Kg	Sciegen Pharmaceuticals INC, USA	0.47
4	1701112170	1701113405	l8-Sep-2017	7-Oct-2017	17-Sep-20	90.92 Kg	Sciegen Pharmaceuticals INC, USA	0.15
5	1701112501	1701113406	20-Sep-17	7-Oct-2017	19-Sep-20	93.02 Kg	Sciegen Pharmaceuticals INC, USA	1.61
6	1701112056	1701113407	13-Sep-17	7-Oct-2017	12-Sep-20	88.82 Kg	Sciegen Pharmaceuticals INC, USA	0.53
7	1701112558	1701114283	2-Oct-2017	25-Oct-2017	1-Oct-20	63.76 Kg	Sciegen Pharmaceuticals INC, USA	0.6
8	1701112558	1701114284	2-Oct-2017	25-Oct-2017	1-Oct-20	27.06 Kg	Sciegen Pharmaceuticals INC, USA	0.6
9	1701112559	1701114285	3-Oct-2017	25-Oct-2017	2-Oct-2020	91.82 Kg	Sciegen Pharmaceuticals INC, USA	0.45
10	1701112589	1701114286	6-Oct-2017	25-Oct-2017	5-Oct-2020	90.32 Kg	Sciegen Pharmaceuticals INC, USA	0.28
11	1701113300	1701114289	7-Oct-2017	25-Oct-2017	6-Oct-2020	91.32 Kg	Sciegen Pharmaceuticals INC, USA	0.32
12	1701113301	1701114291	8-Oct-2017	25-Oct-2017	7-Oct-2020	90.12 Kg	Sciegen Pharmaceuticals INC, USA	0.32
13	1701113302	1701114708	17-Oct-2017	30-Oct-2017	16-Oct-2020	80.82 Kg	Sciegen Pharmaceuticals	0.85
14	1701113312	1701114709	20-Oct-2017	30-Oct-2017	19-Oct-20	86.82 Kg	Sciegen Pharmaceuticals INC, USA	0.88
15	1701115460	1701117039	23-Nov-17	21-Dec-17	22-Nov-20	16.72 Kg	Sciegen Pharmaceuticals INC, USA	0.31
16	1701115974	1701117040	29-Nov-17	21-Dec-17	28-Nov-20	91.12 Kg	Pharmaceuticals INC, USA	0.26
17	1701115460	1701117041	23-Nov-17	21-Dec-17	22-Nov-20	89.79 Kg	Sciegen Pharmaceuticals INC, USA	0.31
18	1701115738	1701117042	24-Nov-17	21-Dec-17	23-Nov-20	90.42 Kg	Sciegen Pharmaceuticals INC, USA	0.38
19	1701115739	1701117043	25-Nov-17	21-Dec-17	24-Nov-20	89.79 Kg	Sciegen Pharmaceuticals INC, USA	0.44
20	1701115740	1701117044	26-Nov-17	21-Dec-17	25-Nov-20	93.42 Kg	Sciegen Pharmaceuticals INC, USA	0.34
21	1701115741	1701117045	27-Nov-17	21-Dec-17	26-Nov-20	93.72 Kg	Sciegen Pharmaceuticals INC, USA	0.39
22	1701115742	1701117046	28-Nov-17	21-Dec-17	27-Nov-20	93.62 Kg	Sciegen Pharmaceuticals INC, USA	0.31

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