



!" #&/

4;O <548G=>3> 70AB>AC20==O ?@5?0@0BC

(LORANO)

!,:04 ;V:0@AL:>3> 70A>1C:

4VNG0 @5G>28=0: ;>@0B048=;

1 B01;5B:0 @0B048=C 10 <3;

4>?>28=8: ;0:B>78 <=>3V4@0B, <03=VN AB50@0B, :@>E<0;L :C:C@C47O=89, :@5<=VN 4V>:A84
:>:>W4=89 1572>4=89.

V:0@AL:0 D>@<0. "01;5B:8.

V;V >20;L=V B01;5B:8 7 @8A:>N V <0@:C20==O< «LT□10» 7 >4=>3> 1>:C B01;5B:8.

0720 V 465==O 28@>1=8:0.

!0;NB0A \$0@<0 <1%, V<5GG8=0/Salutas Pharma GmbH, Germany (28@>1=8FB2> in bulk, ?0:C20==O,
28?CA: A5@VW).

BB>-2>=-N@V:5-;;5T, 1, 39179 0@;515=, V<5GG8=0/Otto-von-Guericke-Allee, 1, 39179 Barleben, Germany

01>:

5: !.., >;LI0/Lek S. A., Poland (?0:C20==O, 28?CA: A5@VW).

C;.><0=VT2AL:0, 50 !, 02-672 0@H020, >;LI0/Domaniewska str., 50 C, 02-672 Warsaw, Poland.

\$0@<0:>B5@0?52B8G=0 3@C?0.

=B83VAB018 4;O A8AB5<=>3> 70AB>AC20==O. >4 " ! R06A X13.

>@0B048= 0=B83VAB0:0B>@ ?5@8D5@8G=8E 1-3VAB028E @5F5?B>@V2. @8 70AB>AC20==V C @5:>
<5=4>20=V9 4>7V =5 <0T ;;V=VG=> 7=0GCI>W A540B82=>W B0 0=B8E>;V=5@3VG=>W 4VW. @>BO3>
< B@820;>3> ;V:C20==O =5 1C;> 28O2;5=> 6>4=8E ;;V=VG=> 7=0GCI8E 7:07=8:0E 68BBT2> 206;828E
DC=:FV9, ;01>@0B>@=8E 4>A;V465==OE, 40=8E DV78:0;L=>3> >1AB565==O E2>@>3> 01> 2
5;5:B@>:0@4V>3@0@0B048= =5 <0T 7=0GCI>3> 2?;82C =0 0:B82=VABL2-3VAB028E @5F5?B>@V2, =5
1;>:CT 70E20B =>@5?V=5D@8=C B0 D0:B8G=> =5 2?;820T =0 A5@F52>-AC48==C A8AB5=0
0:B82=VABL 2>4VO @8B

VA;O ?5@>@0;L=>3> ?@89>@0B048= 4>1@5 2A<:BCTBLAO B0 <5B01>;V7CTBLAO ?V4 2?;82><
CYP3A4 B0 CYP2D6 3>;>2=8< G8=>< C 457;>@0B048=. '0A 4>AO3=5==O <0:A8<0;L=>W

:>=F5=B@0FVW ;>@0B048=C B0 457;>@0B048=C C ?;072V AB0=>28BL 1-1,5 3>48=8 B0 1,5-3,7 3>48=8
2V4?>2V4=>. >@0B048= B0 9>3> <5B01>;VB 4>1@5 72O7CNBLAO 7 1V;;0<8 ?;07<8 :@>2V.

V>4>ABC?=VABL ;>@0B048=C B0 457;>@0B048=C ?@O< ?@>?>@FV9=0 4> 4>78.

@89>< W6V =57=0G=> ?>4>26CT G0A 2A<:BC20==O ;>@0B048=C, 0;5 =5 2?;820T =0 ;;V=VG=89
5D5:B.

?0FVT=BV2 7 E@>=VG=8<8 ?>@CH5==O<8 DC=:FVW =8@>: A5@54=V9 ?5@V>4 =0?V2282545==O
;>@0B048=C V 9>3> <5B01>;VBC ACBBT2> =5 2V4@V7=OTBLAO 2V4 B0:>3> 4;O 74>@>28E

?0FVT=BV2. # ?0FVT=BV2 7 E@>=VG=8<8 ?>@CH5==O<8 DC=:FVW =8@>: 35<>4V0;V7 =5 2?;820T =0
D0@<0>:V=5B8:C ;>@0B048=C B0 9>3> 0:B82=>3> <5B01>;VBC.

?0FVT=BV2 7 E@>=VG=8<8 70E2>@N20==O<8 ?5GV=:8 0;:>3>;L=>W 5BV>;>3VW ?V:>2V @V2=V
:>=F5=B@0FVW ;>@0B048=C C ?;072V 7@>AB0NBL C42VGV, B>4V O: D0@<0>:V=5B8G=89

?@>DV;L 0:B82=>3> <5B01>;VBC ACBBT2> =5 2V4@V7=OTBLAO 2V4 B0:>3> 4;O ?0FVT=BV2 7 =>@
<0;L=>N DC=:FVTN ?5GV=:8. 5@V>4 =0?V2282545==O ;>@0B048=C B0 9>3> <5B01>;VBC AB0=>282

24 3>48=8 V 37 3>48= 2V4?>2V4=> B0 71V;LHC202AO 70;56=> 2V4 BO6:>ABV 70E2>@N20==O
?5GV=:8.

>:070==O 4;O 70AB>AC20==O.

!8<0B8G=5 ;V:C20==O 0;5@3VG=>3> @8=VBC B0 E@>=VG=>W V4V>?0B8G=>W :@>?82O=:8.

@>B8?:070==O.

@5?0@0B ?@>B8?:070=89 ?0FVT=B0< 7 ?V428I5=>N GCB;82VABN 4> 0:B82=>W @5G>28=8 01>4> 1C4L-O:>3> V=H>3> :>=5=B0 ?@5?0@0BC.

0;56=V 70E>48 157?5:8 ?@8 70AB>AC20==V.

0FVT=B0< V7 BO6:8< ?>@CH5==O< DC=:FV9 ?5GV=:8 =5>1EV4=> ?@87=0G0B8 <5=HC ?>G0B:>2C 4>7C G5@57 <>6;825 7<5=H5==O ;V@5=AC ;>@0B048=C (@5:><5=4>20=0 ?>G0B:>20 4>70 10 <3 G5@57 45=L).

:07V2:0 4;O E2>@8E =0 FC:@>289 4V015B.

1 B01;5B:0 48=8FL 2C3;52>4V2.

"01;5B:8 7C, B>A>2C20B8 ?0FVT=B0< 7 @V4:VA=8<8 A?04:>28<8 D>@<0<8 =5?5@5=>A8<>ABV 30;0:B>78, =54>AB0B=VABN ;0:B078 01> A8=4@><>3;N:>7>-30;0:B>7=>W <0;L01A>@1FVW. 0AB>AC20==O ?@5?0@0BC =5>1EV4=> ?@8?8=8B8, O:

A>1;82V 70AB5@565==O.

0AB>AC20==O C ?5@V>4 203VB=>ABV 01> 3>4C20==O 3@C44N.

03VB=VABL. 0=8E ?@> 70AB>AC20==O ;>@0B048=C 203VB=8<8 6V=:0<8 4C65 <0;>. >A;V465==O =0 B20@8=0E =5 28O28;8 ?@O<8E 01> =5?@O<8E =530B82=8E 5D5:BV2, I> AB>ACNBLAO @5?@>4C:B82=>W B>:A8G=>ABV. 060=>, O: 70EV4 157?5:8, C=8:0B8 70AB>AC20==O ?@5?0@0BC >@0=> C ?5@V>4 203VB=>ABV.

>4C20==O 3@C44N. \$V78:>-EV 282545==O ;>@0B048=C/<5B01>;VBV2 V7 3@C4=8< <>;>

\$5@B8;L=VABL. 0=V I>4> 2?;82C ?@>4C:BC =0 6V=>GC 01> G>;>2VGC D5@B8;L=VABL 2V4ACB=V.

40B=VABL 2?;820B8 =0 H284:VABL @50:FVW ?@8 :5@C20==V 02B>B@0=A?>@B< 01> @>I>BV 7 V=H8<8 <5E0=V7<0<8.

;V=VG=8E 4>A;V465==OE =5 2V47=0G02AO 2?;82 ?@5?0@0BC =0 H284:VABL @50:FVW ?0FVT=B0. @>B5 ?0FVT=B <0T 1CB8 ?@>V=D>@<>20=89 ?@> 4C65 @V4:VA=V 28?04:8 28=8=:5==O A>;82>ABV 01> 70?0<>@>G5==O, O:V <>6CBL 2?;820B8 =0 740B=VABL :5@C20B8 02B>B@0=A?>@B< 01> ?@0FN20B8 7 V=H8<8 <5E0=V7<0<8.

VB8.

D5:B82=VABL B0 157?5:0 70AB>AC20==O ;>@0B048=C 4VBO< 2V:< 4> 2 @>:V2 =5 2AB0=>2;5=0. @5?0@0B □>@0=>, B01;5B:8, ?@87=0G0B8 4VBO< 7 <0A>N BV;0 1V;LH5 30 :3.

!>AV1 70AB>AC20==O B0 4>78.

!>AV1 70AB>AC20==O. 5@>@0;L=>. "01;5B:8 <>6=0 70AB>A>2C20B8 =570;56=> 2V4 ?@89> >7C20==O.

>@>A;V B0 4VB8 2V:< 2V4 12 @>:V2 A;V4 ?@89<0B8 ?> 1 B01;5BFV (10 <3 ;>@0B048=C) 1 @07 =0 4>1C.

;O 4VB59 C 2VfV 2V4 2 4> 12 @>:V2 4>7C20==O 70;568BL 2V4 <0A8 BV;0. @8 <0AV BV;0 1V;LH5 30 :3:

10 <3 (1 B01;5B:0) 1 @07 =0 4>1C. VBO< 7 <0A>N BV;0 <5=H5 30 :3 70AB>A>2C20B8 ?@5?0@0B C 283;O4V A8@>?C 01> ACA?5=7VW.

0FVT=B8 ;VB=L>3> 2V:C.

5 28<030TBLAO :>@5:FVW 4>7C20==O ;N4O< ;VB=L>3> 2V:C.

0FVT=B8 7 ?>@CH5==O< DC=:FVW ?5GV=:8.

0FVT=B0< 7 ?>@CH5==O<8 DC=:FV9 ?5GV=:8 BO6:>3> ABC?5=O A;V4 ?@87=0G0B8 ?@5?0@0B C =86GV9 ?>G0B:>2V9 4>7V, >A;V;L:8 2 =8E<>6;825 7=865==O ;V@5=AC ;>@0B048=C. ;O 4>@>A;8E V 4VB59 V7 <0A>N BV;0 1V;LH5 30 :3 @5:><5=4>20=0 ?>G0B:>20 4>70 A;;040T 10<3 G5@57 45=L.

0FVT=B8 7 ?>@CH5==O< DC=:FVW =8@>:.

5<0T =5>1EV4=>ABV 2 :>@5:FVW 4>78 4;O ?0FVT=BV2 7 ?>@CH5==O< DC=:FVW =8@>:.

5@54>7C20==O.

5@54>7C20==O ;>@0B048=C ?V428ICT G0AB>BC 28=8:=5==O 0=B8E>;V=5@3VG=8E A87C20==V
2V47=0G0;8AO A>=;82VABL, B0EV:0@4VO B0 3>;>2=89 1V;L. @8 ?5@54>7C20==V @5:×5=4CTBLAO
A8<0B8G=5 B0 ?V4B@8C?@>4>26 =5>1EV4=>3> ?5@V>4C G0AC. 5:>×5=4CNBLAO AB0=40@B=V
70E>48 I>4> 2840;5==O ?@5?0@0BC, O:89 =5 2A<:B02AO 7V H;C=:0: ?@>×820==O H;C=:0, ?@89>×
?>4@V1=5=>3> 0:B82>20=>3> 2C3V;;O 7 2>4>N.
>@0B048= =5 282>48BLAO H;OE× 35<>4V0;V7C; =52V4><>, G8 282>48BLAO ;>@0B048= H;OE×
?5@8B>=50;L=>3> 4V0;V7C.
VA;O =52V4;:04=>W 4>?>×38 ?0FVT=B <0T 70;8H0B8AO ?V4 <548G=8< =03;O4>

>1VG=V 5D5:B8.

4VB59 2V4 2 4> 12 @>:V2 2V47=0G0;8AO B0:V =51060=V O28I0 O: 3>;>2=89 1V;L, =5@2>7=VABL
01> ?V428I5=0 2B><;N20=VABL. # 4>@>A;8E B0 4VB59 2V4 12 @>:V2 2V47=0G0;8AO A>=;82VABL,
3>;>2=89 1V;L, ?V428I5=89 0?5B8B B0 157A>==O.
!>AB5@V30;8AO ?>>48=>:V 28?04:8 =0ABC?=8E ?>1VG=8E 5D5:BV2:

!8AB5<8 >@30=V2	>1VG=V 5D5:B8
	=0DV;0:AVO
5@2>20 A8AB5<0	0?0<>@>G5==O, AC4>×8
!5@F52>-AC48==0 A8AB5<0	"0EV:0@4VO, 2V4GCBBO A5@F518BBO, ?0;L?VB0FVO.
(;C=:>2>-:8H:>289 B@0:B	C4>B0, ACEVABL C @>BV, 30AB@8B
5?0B>1V;V0@=0 A8AB5<0	>@CH5==O ?5GV=:>28E DC=:FV9
(:V@0 B0 ?V4H:V@=0 B:0=8=0	8A8?0==O, 0;>?5FVO
030;L=V ?@>O28	V428I5=0 2B><;N20=VABL

70T<>4VO 7 V=H8<8 ;V:0@AL:8<8 70A>10<8 B0 V=HV 2848 270T<>4V9.
@5?0@0B =5 ?>A8;NT ?@83=VGC20;L=C 4VN 0;:>3>;N =0 ?A8E><>B>@=V @50:FVW.
4=>G0A=5 70AB>AC20==O ;>@0B048=C 7 V=3V1VB>@0<8 CYP3A4 01> CYP2D6 <>65 ?@872>48B8 4>
?V428I5==O @V2=O ;>@0B048=C, I>, C A2>N G5@3C, ?>A8;NT ?>1VG=V 5D5:B8.
@8 >4=>G0A=>AC20==V ;>@0B048=C 7 :5B>:=>07>;×, 5@8B@>×, F8<5B848=>× 2V47=0G0;>AO
?V428I5==O :>=F5=B@0FVW ;>@0B048=C C ?;072V, 0;5 F5 ?V428I5==O =5 28O2;O;>AO ;:V=VG=>, C B>
VB8. >A;V465==O 270T<>4V9 7 V=H8<8 ?@5?0@0B0<8 ?@>2>48;8AO BV;L:8 7 CG0ABN 4>@>A;8E
?0FVT=BV2.

"5@ABV.3 @>:8.

#<>28 715@V30==O.

!>5FV0;L=8E C<>2 715@V30==O =5 ?>B@51CT.
15@V30B8 C =54>ABC?=>

#?0:>2:0.

> 7 01> ?> 10 B01;5B>: C 1;VAB5@V; ?> 1 (7□ 1) 01> 2 (10□ 2) 1;VAB5@8 2 :0@B>==V9 :>@>1FV.

0B53>@VO 2V4?CA:C. 57 @5F5?B0.